PALATIN TECHNOLOGIES INC Form 10-K405 September 28, 2001

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

#### FORM 10-K

#### [X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2001

OR

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

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

Commission file number 0-22686

#### PALATIN TECHNOLOGIES, INC. (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

103 Carnegie Center - Suite 200 Princeton, New Jersey (Address of principal executive offices)

Registrant's telephone number, including area code: (609) 520-1911

Securities registered pursuant to Section 12(b) of the Exchange Act:

Common Stock, par value \$.01 per share (Title of class)

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 [X] No []

1

95-4078884

(I.R.S. Employer Identification No.)

08540 (Zip Code)

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was sold, as of September 27, 2001, was \$26,959,491.

As of September 27, 2001, 11,199,611 shares of the issuer's common stock, par value \$.01 per share, were outstanding.

Documents incorporated by reference: the registrant's definitive proxy statement relating to the annual meeting of stockholders currently scheduled for November 2001, incorporated by reference in Part III of this Form 10-K.

# TABLE OF CONTENTS

#### PART I

Item 1.	Business	Page 4
Item 2.	Properties	Page 14
Item 3.	Legal Proceedings	Page 14
Item 4.	Submission of Matters to a Vote of Security Holders	Page 15

#### PART II

Item 5.	Market for Registrant's Common Equity and Related Stockholder Matters	Page 16
Item 6.	Selected Financial Data	Page 17
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	Page 19
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	Page 28
Item 8.	Financial Statements and Supplementary Data	Page 30

#### Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Page 52 Disclosure

#### PART III

Item 10.	Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act	Page 53*
Item 11.	Executive Compensation	Page 53*
Item 12.	Security Ownership of Certain Beneficial Owners and Management	Page 53*
1 2	Certain Relationships and Related Transactions reference from our definitive proxy statement relating to the 2001 Annual Meeting of Stoc e with the Securities and Exchange Commission within 120 days after our June 30, 2001 fi	-

#### PART IV

Item 14.	Exhibits, Financial Statement Schedules and Reports on Form 8-K	Page 53
<u>Signatures</u>		Page 58

Table of Contents

end.

# PART I

#### Item 1. Business.

# **Forward-looking statements**

We make forward-looking statements in this report and the documents we incorporate by reference. Sometimes these statements contain words such as "anticipates," "plans," "intends," "expects" and similar expressions to identify forward-looking statements. These statements are not guarantees of our future performance. Our business involves known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from what we say in this report and in the documents we incorporate by reference. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. We may not revise these forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

#### Overview

We are a development-stage pharmaceutical company committed to the discovery, development and commercialization of novel therapeutics. We do not currently offer any products for sale. We are concentrating our efforts on the following:

- o **MIDAS (Metal Ion-induced Distinctive Array of Structures)** is our proprietary technology platform for drug design. This technology may be useful to develop drugs to treat diseases or for diagnostic imaging. We are engaged in research and development using this technology to diagnose infections and treat sexual dysfunction, obesity and inflammation, and believe that this technology may have applications in a variety of other areas as well, including immune disorders, cancers and cardiology.
- o **PT-141** is a new, nasally administered peptide for the treatment of sexual dysfunction. Our research suggests that PT-141 works through a mechanism involving the central nervous system. We began human clinical testing of PT-141 for erectile dysfunction in the first quarter of calendar 2001. We have completed a Phase 1 study and anticipate initiating a Phase 2 efficacy trial later in this calendar year.
- o **LeuTech**® is a product in development that is to be used to rapidly image and diagnose sites of infection. The FDA Medical Imaging Drugs Advisory Committee unanimously voted that LeuTech is safe and effective for the diagnosis of appendicitis. The FDA reviewed the biologics license application (BLA) and determined that the efficacy and safety data are complete, yet additional manufacturing and process validation data were required prior to final approval. We are working to resolve the outstanding issues and intend to file an amendment to the BLA in the latter part of calendar year 2002. We are testing LeuTech for detection of other infections, including osteomyelitis (infection deep inside a bone), which is now in Phase 2 studies.

4

#### Table of Contents

#### Products and Technologies in Research and Development

In order to understand the process of drug testing and approval, it is helpful to be familiar with the following terminology of clinical trial phases and FDA applications:

Preclinical testing: animal trials to evaluate toxicity.

*Phase 1:* In Phase 1 clinical trials, researchers test a new drug or treatment in a small group of patients for the first time to evaluate its safety.

*Phase 2:* In Phase 2 clinical trials, the study drug or treatment is given to patients to see if it is effective, to determine a safe dosage range and to further evaluate its safety.

*Phase 3:* In Phase 3 studies, the study drug or treatment is given to a large group of patients to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will support product approval.

*Investigational new drug application, or IND:* report on preclinical testing and intended clinical testing through Phase 3, with manufacturing and labeling information.

*Biologics license application, or BLA:* application for FDA approval for sale of a product classified as a biologic.

New Drug Application: application for FDA approval for sale of a product classified as a drug.

MIDAC: Medical Imaging Drug Advisory Committee.

*MIDAS* is a proprietary technology platform that allows us to routinely design and synthesize novel pharmaceuticals that mimic the activity of peptides but offer significant advantages to conventional protein or peptide-based drugs. MIDAS uses metal ions to fix the three-dimensional shape of peptides, forming conformationally rigid molecules that remain folded specifically in their active forms. These MIDAS molecules are simple to synthesize, stable chemically and proteolytically, and have the potential to be orally bioavailable. Moreover, unlike most other drug discovery approaches, MIDAS is unique in that it can be used to generate either receptor antagonists (drugs that block a particular metabolic response) or agonists (drugs that promote a particular metabolic response). In addition, MIDAS molecules are information-rich and provide data on structure-activity relationships that can be used to design traditional small molecule drugs.

We have initiated a MIDAS program to discover and develop compounds that interact with the melanocortin (MC) family of receptors. MC receptors regulate a diverse array of

5

#### Table of Contents

functions such as pigmentation, adrenocortical function, immune modulation, sexual arousal and energy maintenance. Based on this effort, we have identified several MIDAS molecules that are now in preclinical development as potential treatments for obesity and inflammation. Additionally, we have identified molecules that interact with receptors on cancer cells; one of these molecules is now in preclinical development as a potential treatment for cancer. We expect to file INDs for at least one of these preclinical compounds and initiate clinical testing within two years.

Generation of commercially viable protein and peptide drug molecules with desirable properties continues to be arduous, expensive and labor-intensive. We believe that our MIDAS technology simplifies the development process by eliminating many of the inherent limitations associated with peptides and proteins. We intend to seek to enter into strategic alliances or collaborative arrangements to provide additional financial and technical resources for MIDAS development.

**PT-141.** PT-141 is our lead therapeutic drug candidate and it is now in development for the treatment of erectile dysfunction (ED). PT-141 works through a novel mechanism of action. Company research suggests this mechanism may involve the central nervous system which is different from currently marketed ED therapies. We believe PT-141 has the potential to treat both male and female sexual dysfunction and that it may offer significant benefits in terms of safety and efficacy over currently marketed products. We have completed our Phase 1 human safety evaluation and plan to commence our Phase 2 human efficacy trials later this calendar year. In addition, we anticipate beginning a "proof-of-concept" clinical study in female sexual dysfunction in the next calendar year.

Studies indicate that as many as 30 million men in the United States may be afflicted with some form of male erectile dysfunction. Because of the large number of men believed to be afflicted with male erectile dysfunction, we believe the total market for treatment will be several billion dollars per year. There is tremendous competition to develop and market drugs for treatment of male erectile dysfunction.

*LeuTech.* LeuTech is a radiolabeled monoclonal antibody that is intended to image and diagnose sites of infection. When injected into the blood stream, LeuTech binds to white blood cells present at the infection site, labeling these cells with the radioactive tracer. As a result, physicians can rapidly image and detect an infection using a gamma camera, a common piece of hospital equipment that records radioactivity. In July 2000, the FDA MIDAC panel unanimously recommended the approval of LeuTech for use in diagnosing appendicitis in patients with equivocal signs and symptoms. Currently, we are responding to the FDA's request for additional

6

#### Table of Contents

manufacturing and process validation information in accordance with their complete review letter dated September 23, 2000. We anticipate completing the steps necessary for the filing of amendments to the BLA in the latter part of calendar 2002. We are conducting additional clinical trials with LeuTech to diagnose other infections such as bone infections, infections of prostheses, or artificial body parts, and abscesses. We believe that LeuTech can be used to diagnose a wide range of other infections, including infections of the intra-abdominal area, such as intestinal, spleen, liver or urinary tract infections.

*Strategic Collaboration Agreement with Mallinckrodt.* On August 16, 1999, we entered into a strategic collaboration agreement with Mallinckrodt, Inc., a large international healthcare products company, to jointly develop and market LeuTech. In October 2000, Tyco International, Ltd. acquired Mallinckrodt.

*Research and Development.* Our research and development efforts primarily focus on two areas: diagnostic imaging and therapeutics. By combining these areas, we believe our technologies will facilitate the development of a portfolio of potential products. Our current product development efforts are focused on three areas:

- o LeuTech, a patented, radiolabeled monoclonal antibody product under investigation for imaging and diagnosing infections.
- o PT-141, a novel, nasally administered peptide under investigation for the treatment of both male and female sexual dysfunction.
- o MIDAS, a powerful, patented drug discovery platform, which:
  - o Enables the rapid, systematic design and synthesis of rigid, peptide-derived compounds for drug development.
  - o Provides an in depth understanding of receptor-ligand interactions and structure-activity relationships which give us a valuable tool for the structure-based design of small molecule compounds and additionally provides powerful tools for use in drug target validation.

A summary of our research and development program appears below. Research includes the identification of novel molecular targets, development of assay systems, discovery and evaluation of prototype compounds in vitro and in vivo with animal testing. Development includes product formulation, toxicology and additional animal testing of a compound followed by clinical testing and manufacturing methods development.

LeuTech	Equivocal Appendicitis	Pending FDA Approval	Mallinckrodt
	Osteomyelitis - Prosthetic Joint Infection	Phase 2	Mallinckrodt
	Osteomyelitis - Diabetic Foot Ulcers	Phase 2	Mallinckrodt
PT-141	Erectile Dysfunction	Phase 1 complete, Phase 2 to begin later this calendar year	
	Female Sexual Arousal Disorder	Proof of concept clinical study to begin next calendar year	
PT-15 (MIDAS compound)	Obesity	Preclinical	
PT-16 (MIDAS compound)	Cancer Treatment	Preclinical	
Anti-Inflammatory agent	Inflammation/Ischemia	Preclinical	

Over the last three fiscal years, we have spent approximately the following amounts on company-sponsored research and development activities:

- o year ended June 30, 2001: \$10,109,000
- o year ended June 30, 2000: \$ 9,110,000

o year ended June 30, 1999: \$ 8,720,000

# **Patents and Proprietary Information**

*Patent protection.* Our success will depend in substantial part on our ability to obtain, defend and enforce patents, maintain trade secrets and operate without infringing upon the proprietary rights of others, both in the United States and abroad. We aggressively seek patent protection for our technology in the United States and, selectively, in those foreign countries where protection is important to the development of our business.

We own or have rights to patents and pending applications directed to radiolabeling of antibodies, antibody fragments, and peptides; MIDAS peptides; peptide pharmaceuticals; and to methods for making and using the foregoing in diagnostic and therapeutic applications. We own or have rights to over 25 United States patents, several pending United States patent applications, and foreign patents and applications in selected foreign countries corresponding to certain United States patents and applications.

We have exclusive rights to patents relating to PT-141, as well as to pending applications covering PT-141. We may not be able to obtain patents covering PT-141, and the claims of any patents that

9

#### Table of Contents

issue may not provide meaningful protection for PT-141. In addition, even if such patents issue they may not be valid.

We own patents covering certain aspects of the LeuTech product, but the claims of those patents may not be effective to prevent others from developing competing products. In addition, the validity of these patents has not been

#### determined.

In the event that a third party has also filed a patent application relating to an invention we claimed in a patent application, we may be required to participate in an interference proceeding adjudicated by the United States Patent and Trademark Office to determine priority of invention. The possibility of an interference proceeding could result in substantial uncertainties and cost, even if the eventual outcome is favorable to us. An adverse outcome could result in losing patent protection for the subject of the interference, subjecting us to significant liabilities to third parties and requiring us to obtain licenses from third parties at undetermined cost or to cease using the technology.

*Future patent infringement.* We do not know for certain that our commercial activities will not infringe upon patents or patent applications of third parties, some of which may not even have been issued yet. Although we are not aware of any valid U.S. patents which are infringed by LeuTech or by our method of making LeuTech, we cannot exclude the possibility that such patents might exist or arise in the future. We may be unable to avoid infringement of any such patents and may have to seek a license, defend an infringement action, or challenge the validity of such patents in court. Patent litigation is costly and time consuming. If we do not obtain a license under any such patents, are found liable for infringement, or if such patents are not found to be invalid, we may be liable for significant money damages, may encounter significant delays in bringing products to market, or may be precluded from participating in the manufacture, use or sale of products or methods of treatment covered by such patents.

*Government rights.* Some of our patents are directed to inventions developed internally or within academic institutions from which we previously acquired rights to such patents with funds from United States government agencies. As a result of these arrangements, the United States government may have rights in certain inventions developed during the course of the performance of federally funded projects, as required by law or agreements with the funding agency.

*Proprietary information.* We rely on proprietary information, such as trade secrets and know-how, which is not patented. We have taken steps to protect our unpatented trade secrets and know-how, in part through the use of confidentiality agreements with our employees, consultants and certain contractors. If our employees, scientific consultants or collaborators or licensees develop inventions or processes independently that may be applicable to our product candidates, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may

10

#### Table of Contents

remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights.

If trade secrets are breached, our recourse will be solely against the person who caused the secrecy breach. This might not be an adequate remedy to us, because third parties other than the person who causes the breach will be free to use the information without accountability to us. This is an inherent limitation of the law of trade secret protection.

# **Governmental Regulation**

The FDA, comparable agencies in foreign countries and state regulatory authorities have established regulations and guidelines which apply, among other things, to the clinical testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, promotion and marketing of our proposed products. Noncompliance with applicable requirements can result in fines, recalls or seizures of products, total or partial suspension of production, refusal of the regulatory authorities to approve marketing applications, and criminal prosecution.

After approving a product for marketing, the FDA may require post-marketing testing, including extensive Phase 4 studies, and surveillance to monitor the effects of the product in general use. The FDA may withdraw product approvals if compliance with regulatory standards is not maintained or if problems occur following initial marketing. In addition, the FDA may impose restrictions on the use of a drug that may limit its marketing potential.

*Good manufacturing practices.* In addition to obtaining either a biologics license application or new drug application approval from the FDA for any of our proposed products, if the proposed product is manufactured in the United States, the drug manufacturing establishment must be registered with, and inspected by, the FDA. Such drug manufacturing establishments are subject to biennial inspections by the FDA, and must comply with good manufacturing establishments must comply with good manufacturing establishments must comply with good manufacturing practices regulations enforced by the FDA. To supply products for use in the United States, foreign manufacturing establishments must comply with good manufacturing practices and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in such other countries under reciprocal agreements with the FDA. In complying with standards established by the FDA, manufacturing establishments must continue to expend time, money and effort in the areas of production and quality control to ensure full technical compliance. We depend on contract manufacturing establishments, both in the United States and in foreign countries, to manufacture components of LeuTech. We anticipate that contract manufacturing establishments will manufacture PT-141 and proposed products resulting from MIDAS technology.

# **Third-Party Reimbursements**

Successful sales of our proposed products in the United States and other countries will depend on the availability of adequate reimbursement from third-party payors such as governmental entities, managed care organizations and private insurance plans. Reimbursement by a third-party payor may depend on a number of factors, including the payor's determination

#### Table of Contents

that use of a product is safe and efficacious, neither experimental nor investigational, medically necessary, appropriate for the specific patient and cost effective. Since reimbursement approval is required from each payor individually, seeking such approvals is a time-consuming and costly process. Third-party payors routinely limit reimbursement coverage and in many instances are exerting significant pressure on medical suppliers to lower their prices. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology, and we are not sure whether third-party reimbursement will be available for our proposed products, or that the reimbursement, if obtained, will be adequate. Less than full reimbursement by governmental and other third-party payors for our products would adversely affect the market acceptance of these products. Further, health care reimbursement systems vary from country to country, and we are not sure whether third-party reimbursement will be made available for our proposed products under any other reimbursement system.

#### Manufacturing and Marketing

To be successful, our products must be manufactured in commercial quantities under current good manufacturing practices requirements prescribed by the FDA and at acceptable costs. We do not have the facilities to manufacture any products in commercial quantities under good manufacturing practices. We intend to rely on collaborators, licensees or contract manufacturers for the commercial manufacture of our products.

We are dependent on Dutch State Mines of the Netherlands for the manufacture of the antibody used in LeuTech, and on Ben Venue Laboratories of Cleveland, Ohio for the manufacture of LeuTech kits. The failure of either of these manufacturers to comply with FDA current good manufacturing practices or to supply these key components of LeuTech on a timely basis or at all, could force us to seek alternative sources of supply and could interfere with our

ability to deliver product on a timely basis or at all. Establishing relationships with new suppliers, any of whom must be FDA-approved, is a time-consuming and costly process.

If LeuTech is approved for marketing by the FDA, we will rely on our arrangement with Mallinckrodt/Tyco to market, sell and distribute LeuTech. We will have limited control over these activities.

Proposed products resulting from MIDAS technology and PT-141 are synthetic peptides. The peptides are synthesized from readily available amino acids, and the production process involves well-established technology. We currently contract with third-party manufacturers for the production of peptides and anticipate doing so in the future.

We intend to package and ship our radiopharmaceutical products in the form of non-radioactive kits. Prior to patient administration, the product would be radiolabeled with the specified radioisotope, generally by a specialized radiopharmacy. We do not intend to sell or distribute any radioactive substance.

12

#### Table of Contents

# **Product Liability and Insurance**

Our business may be affected by potential product liability risks which are inherent in the testing, manufacturing and marketing of our proposed products. We have liability insurance providing up to \$5,000,000 coverage per occurrence and in the aggregate as to certain clinical trial risks, and we will seek to obtain additional product liability insurance before the commercialization of our products.

#### **Employees**

We currently employ 33 persons full time, of whom 26 are engaged in research and development activities and seven are engaged in administration and management. Fourteen of our employees hold Ph.D. degrees and one is an M.D. We have been successful in attracting skilled and experienced scientific personnel, however, competition for personnel in our industry is intense.

None of our employees are covered by a collective bargaining agreement. Our employees have executed confidentiality agreements. We consider relations with our employees to be good.

From time to time, we hire scientific consultants to work on specific research and development programs. We also rely on independent organizations, advisors and consultants to provide services, including most aspects of manufacturing and some aspects of regulatory approval and clinical management. Our independent advisors and consultants generally sign agreements that provide for confidentiality of our proprietary information.

#### **History and Merger**

*Interfilm, Inc.* Palatin was incorporated as a Delaware corporation on November 21, 1986 under the name of Cinedco, Inc., which it later changed to Interfilm, Inc. From 1993 to 1995, Interfilm was primarily engaged in the interactive motion picture business. Interfilm suspended its business activities in May 1995.

*RhoMed merger.* On June 25, 1996, Interfilm merged with RhoMed Incorporated, a New Mexico corporation engaged in biotechnology research and development. All of RhoMed's outstanding equity securities were exchanged for equity securities of Interfilm, and Interfilm changed its legal name to Palatin Technologies, Inc. The business of RhoMed became the ongoing business of Palatin. RhoMed remains as a wholly-owned, inactive subsidiary of Palatin.

New name and capital restructuring. On July 19, 1996, we amended our certificate of incorporation to:

0	change our name from Interfilm, Inc. to Palatin Technologies, Inc.,
0	increase our authorized common stock from 10,000,000 to 25,000,000 shares, and
0	effect a 1-for-10 reverse split of the common stock. 13

#### Table of Contents

On September 5, 1997, we again amended our certificate of incorporation, to:

- o increase our authorized common stock from 25,000,000 to 75,000,000 shares,
- o increase our authorized preferred stock from 2,000,000 to 10,000,000 shares, and
- o effect a 1-for-4 reverse split of the common stock.

#### Item 2. Properties.

Our corporate offices are located at 103 Carnegie Center, Suite 200, Princeton, New Jersey, where we lease approximately 7,300 square feet under a lease which expires December 15, 2004. Our research and development facility is located in Edison, New Jersey, where we lease approximately 16,000 square feet under a lease which expires July 31, 2007. The leased properties are in good condition.

During 2001, we entered into an agreement to lease a new facility of approximately 28,000 square feet in Cranbury, New Jersey that will combine both the corporate offices in Princeton and the research and development facility in Edison. The lease is subject to our approval of certain conditions of the lease and would expire 10 years from commencement. Subject to our acceptance or renegotiation of these conditions, we would anticipate occupying the new space in the first quarter of calendar year 2002. Should we be unable to negotiate acceptable final terms, we could terminate the agreement. Our anticipated cash outlay related to the move is projected at \$1.6 million.

# Item 3. Legal Proceedings.

On March 14, 2000 we announced that we would not be extending the merger closing date of March 31, 2000 for our previously announced proposed merger with San Diego-based Molecular Biosystems, Inc. and will not be proceeding with the merger. Our decision not to proceed with the merger was based on management's view that the merger was not in the best interests of our stockholders.

On or about April 28, 2000, Molecular Biosystems commenced a legal action against us and against Evergreen Merger Corporation, a wholly-owned subsidiary of the Company, in the Superior Court of the State of Delaware, County of New Castle. In the complaint, Molecular Biosystems seeks damages against us and Evergreen arising from the alleged improper termination of the merger agreement dated November 11, 1999, among Molecular Biosystems, Palatin and Evergreen. Under the merger agreement, Evergreen would have merged with and into Molecular Biosystems, which would have become a wholly-owned subsidiary of ours.

As a consequence of the claims alleged in the complaint, Molecular Biosystems contends that it is entitled to an award of damages against us and Evergreen in amounts to be determined at trial, but in any event, at least equal to \$1,765,305. This figure represents the amount of a "breakup fee" of \$1,000,000 provided for in the agreement and \$765,305 for the purported costs

14

and expenses allegedly incurred by Molecular Biosystems in connection with the proposed merger. In addition, Molecular Biosystems seeks consequential damages in an unstated amount plus interest and Molecular Biosystems' costs and expenses of the action.

In our response filed in June of 2000, we have denied the material allegations. Management believes that we have good and meritorious defenses to the action and we intend vigorously to defend the action. On January 3, 2001, Alliance Pharmaceutical Corp. (NASDAQ: ALLP) announced that it had completed its acquisition of Molecular Biosystems. This litigation is currently in the discovery and deposition phase.

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

We did not submit any matters to a vote of security holders during the fourth quarter of the fiscal year ended June 30, 2001.

15

Table of Contents

#### PART II

#### Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

Our common stock has been quoted on The American Stock Exchange under the symbol PTN, since December 21, 1999. It had previously traded on the Nasdaq SmallCap Market under the symbol PLTN.

The table below provides, for the fiscal quarters indicated, the reported high and low closing sales prices for the common stock on AMEX since December 21, 1999, and the reported high and low bid prices for the common stock on Nasdaq before December 21, 1999.

YEAR ENDED JUNE 30, 2001	HIGH	LOW
Fourth Quarter	\$ 6.560	\$ 2.250
Third Quarter	\$ 4.625	\$ 2.000
Second Quarter	\$ 6.125	\$ 2.563
First Quarter	\$ 8.188	\$ 4.938
YEAR ENDED JUNE 30, 2000	HIGH	LOW
Fourth Quarter	\$ 7.375	\$ 3.250
Third Quarter	\$ 9.750	\$ 2.625
Second Quarter	\$ 4.063	\$ 2.250
First Quarter	\$ 5.188	\$ 2.969

*Holders of common stock.* On September 27, 2001, we had approximately 282 holders of record of common stock. On September 27, 2001 the closing sales price of our common stock as reported on the AMEX was \$3.10 per share.

*Dividends and dividend policy.* We have never declared or paid any dividends. We currently intend to retain earnings, if any, for use in our business. We do not anticipate paying dividends in the foreseeable future.

*Dividend restrictions.* Our two outstanding series of preferred stock, Series A and C, contain the following restrictions on our ability to pay dividends or make distributions to stockholders.

- o Series A: We may not pay a dividend or make any distribution to holders of any class of stock unless we first pay a special dividend or distribution of \$100 per share to the holders of Series A preferred stock.
- o Series C: We may not pay a dividend or make any distribution to holders of any class of stock while any Series C preferred stock remains outstanding.

16

#### Table of Contents

*Recent sales of unregistered securities.* There were no sales, which were not previously disclosed, of securities of Palatin sold by Palatin during the year ended June 30, 2001, which were not registered under the Securities Act.

#### Item 6. Selected Financial Data.

The following selected consolidated financial data has been derived from the consolidated financial statements of Palatin Technologies, Inc. as of and for each of the five years in the period ended June 30, 2001, which have been audited by Arthur Andersen LLP, independent public accountants. This data should be read in conjunction with our consolidated financial statements, including the notes to the financial statements, and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of this report.

#### **Selected Financial Data**

(In thousands, except per share dat

		Year	Ended June 3	30,	
1997		1998	1999		20
\$ 350	\$	34	\$ 60	)\$	4
350			550	)	
22				-	
 722		34	610	)	5
3,410		7,111	8,720	)	ç
2,533		2,991	3,95	1	4
 5,943		10,102	12,67		13
296		409	172	2	
\$	\$ 350 350 22 722 3,410 2,533 5,943	\$ 350 \$ 350 22 	$\begin{array}{c} & & & \\ & & & & \\ & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

#### Table of Contents

Selected Financial Data

(continued)

(In thousands, except per share dat

Year Ended June 30,

		1997		1998	1999	_	20
Interest expense		(375)		(227)			
Total other income/(expense)		(79)		182	65		
Loss before income taxes & cumulative effect of accounting change				(9,886)			(8
Income tax benefit					 		
Loss before cumulative effect of accounting change	ſ	(5,300)		(9,886)	(12,002)		(8
Cumulative effect of accounting change (1)					 		
NET LOSS		(5,300)		(9,886)	(12,002)		(8
PREFERRED STOCK DIVIDEND		(2,889)		(233)	 		
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS		(8,189)			(12,002)	 \$	(8
Basic and diluted net loss before cumulative effectof accounting change		(2.80)			(2.02)	 \$	(
Cumulative effect of accounting change (1)							
Basic and diluted net loss per common share		(2.80)					(
Weighted average common shares outstanding				3,211	5,936		7
Pro forma amounts assuming accounting change applied retroactively:		=	=		 	_ =	
Net loss to common shareholders	\$	(8,189)	\$	(10,119)	\$ (12,002)	\$	(8
Basic and diluted net loss per common share	\$	(2.80)	\$	(3.15)	\$ (2.02)	\$	(

#### 18

#### Table of Contents

# **Selected Financial Data**

# (continued)

	(	In Thousands)		
		June 30,		
1997	1998	1999	2000	2001

Balance Sheet Data:

Item 6. Selected Financial Data.

Stockholders' equity	\$	9,835	\$ 3,390	\$ 341	\$ 6,905	\$ 11,91
Long term debt, net of current portion		940	-	2,000	-	
Total assets		14,063	6,475	4,723	8,885	14,24
Working capital		10,142	2,069	554	4,995	9,36
Property & equipment, net		922	1,610	1,458	1,573	1,92
Cash, cash equivalents and investments	Ş	12,622	\$ 4,326	\$ 2 <b>,</b> 789	\$ 5,842	\$ 11,45

(1) In fiscal 2001, we recorded a non-cash charge for the cumulative effect related to the adoption of SEC Staff Accounting Bulletin No. 101. See note 2 to the Consolidated Financial Statements.

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes to the financial statements filed as part of this report.

#### Significant Events in Fiscal Year 2001

In September and October of 2000, we received aggregate gross proceeds of \$15.15 million in a private placement of common stock and warrants. Investors, consisting of European financial institutions and other foreign accredited investors, purchased approximately 2.5 million shares of common stock in two tranches: 1,800,000 shares at \$6.00 per share and 732,368 shares at \$5.94 per share. For every five shares purchased, the investors also received a five-year warrant to purchase one share of common stock at an exercise price of \$7.50 for the first tranche and \$7.42 for the second tranche. The net proceeds of approximately \$14 million continue to be used primarily for general corporate purposes, especially for the development and clinical trials of new products based on our proprietary technologies.

19

#### Table of Contents

In July 2000, the FDA MIDAC panel unanimously recommended the approval of LeuTech for use in diagnosing appendicitis in patients with equivocal signs and symptoms. Currently, we are responding to the FDA's request for additional manufacturing and process validation information in accordance with their complete review letter dated September 23, 2000. We anticipate completing the steps necessary for the filing of amendments to the BLA in the latter part of calendar 2002.

#### **Results of Operations**

Year Ended June 30, 2001 Compared to the Year Ended June 30, 2000

*Grants and contracts* - Contract revenue, related to the shared development costs of LeuTech pursuant to our collaboration agreement with Mallinckrodt, Inc. decreased to \$1,410,356 for the year ended June 30, 2001 as compared to \$4,141,480 reported for the year ended June 30, 2000. The decrease was attributable to the cap on shared development costs of LeuTech pursuant to the agreement. Grant revenue under the Small Business Innovation Research and the Small Business Technology Transfer programs of the Department of Health and Human Services

decreased to \$211,069 for the year ended June 30, 2001 compared the \$475,631 reported for the year ended June 30, 2000.

*License Fees and Royalties* - During the year ended June 30, 2001, we adopted U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements" ("SAB 101"), which requires up-front, non-refundable license fees to be deferred and recognized over the performance period. The cumulative effect of adopting SAB 101 resulted in a one-time, non-cash charge of \$361,111 or \$0.04 per share, which reflects the deferral of an up-front license fee received from Mallinckrodt, Inc. related to licensing of LeuTech recognized in the year ended June 30, 2000. Previously, we had recognized up-front license fees when they were received and we had no obligations to return the fees under any circumstances. Under SAB 101 these payments are recorded as deferred revenue to be recognized over the remaining term of the related agreements. For the year ended June 30, 2001, we recorded \$166,667 of license revenue that was included in the cumulative effect adjustment as of July 1, 2000. Our year ended June 30, 2000 and 1999 results have not been restated to apply SAB 101 retroactively.

*Research and development* - Research and development (R&D) expenses increased to \$10,108,999 for the year ended June 30, 2001 compared to \$9,109,619 for the year ended June 30, 2000. The increase in R&D is primarily related to our increased development efforts and expanding clinical trials of PT-141 and research on our MIDAS Technology.

*General and administrative* General and administrative (G& A) expenses decreased to \$3,024,841 for the year ended June 30, 2001 compared to \$4,567,273 for the year ended June 30, 2000. The decrease in G&A is mainly attributable to the decrease in administrative salaries and payments made in fiscal 2000 related to a terminated merger and significant non-cash, stock based compensation expense recorded in fiscal 2000.

*Interest income* - Interest income increased to \$787,574 for the year ended June 30, 2001 compared to \$405,590 for the year ended June 30, 2000. The increase in interest income is due

20

#### Table of Contents

to higher level of funds available for investment due to our financing in September and October of 2000.

*Interest expense* - Interest expense decreased to \$5,104 for the year ended June 30, 2001 compared to \$29,247 for the year ended June 30, 2000. The decrease in interest expense was due to the repayment of debt that occurred during the three months ended September 30, 1999.

*Net Loss* - Increased to \$10,599,237 for the year ended June 30, 2001 compared to \$8,183,438 for the year ended June 30, 2000. The increase is due to the reduction in grant and contract revenue and the increase in research and development expenses explained above.

#### Year Ended June 30, 2000 Compared to the Year Ended June 30, 1999

*Grants and contracts* - We recorded \$4,141,480 as contract revenue during the year ended June 30, 2000 related to the shared development costs and product direct costs of LeuTech, pursuant to our strategic collaboration agreement with Mallinckrodt. We also recorded \$475,631 as grant revenue for the year ended June 30, 2000. We completed Phase I grants and a Phase II grant, previously awarded, under the Small Business Innovative Research program with the National Institutes of Health of the Department of Health and Human Services. We had no revenues from contracts and recorded \$59,977 as grant revenue for the year ended June 30, 1999.

*License Fees and Royalties* - We recorded \$500,000 in license fees as revenue for the year ended June 30, 2000. We received these fees as a one-time, non-refundable payment pursuant to our strategic collaboration agreement with Mallinckrodt. We recognized \$550,000 in license fees as revenue during the year ended June 30, 1999 related to our license option agreement with Nihon Medi-Physics. We recognized this \$550,000, previously recorded as "deferred revenue," because we and Nihon changed the development emphasis and termination provisions of the original agreement. We are not required to perform any future services under this agreement.

*Research and development* - Research and development expenses increased to \$9,109,619 for the year ended June 30, 2000 compared to \$8,719,562 for the year ended June 30, 1999. The increase in R&D is primarily related to development of our LeuTech product, including increased expenses for manufacturing scale-up, consulting and clinical trials. We expect research and development expenses to continue to increase in future quarters as we expand clinical trials and manufacturing efforts on the LeuTech product and expand efforts to develop PT-141 and the MIDAS technology.

*General and administrative* - General and administrative expenses increased to \$4,567,273 for the year ended June 30, 2000 compared to \$3,957,401 for the year ended June 30, 1999. The increase in general and administrative expenses was mainly attributable to the payment of approximately \$625,000 of costs pursuant to the proposed merger with Molecular Biosystems.

*Interest income* - Interest income increased to \$405,590 for the year ended June 30, 2000 compared to \$172,241 for the year ended June 30, 1999. The increase in interest income is the

21

#### Table of Contents

result of the receipt of funds pursuant to our strategic collaboration agreement with Mallinckrodt, which enabled an increase in funds available for investment purposes.

*Interest expense* - Interest expense decreased to \$29,247 for the year ended June 30, 2000 compared to \$107,639 for the year ended June 30, 1999. The decrease in interest expense is due to the repayment of debt due to Mallinckrodt.

*Net loss* - Net loss decreased to \$8,183,438 for the year ended June 30, 2000 compared to \$12,002,384 for the year ended June 30, 1999. The decrease is attributable to revenues earned related to cost sharing provisions pursuant to the collaboration agreement with Mallinckrodt.

#### Liquidity and Capital Resources

Since inception, we have incurred net operating losses. As of June 30, 2001, we had a deficit accumulated during the development stage of \$54,105,039. We have financed our net operating losses through June 30, 2001 by a series of debt and equity financings. At June 30, 2001, we had cash and cash equivalents of \$11,456,424.

For the year ended June 30, 2001, the net increase in cash and cash equivalents amounted to \$8,236,831. Net cash used for operating activities was \$8,397,357, net cash provided by investing activities was \$1,525,718, and net cash provided by financing activities was \$15,108,470.

In September and October of 2000, we received approximately \$14 million in net proceeds from a private offering consisting of common stock and warrants. Investors, consisting of financial institutions based in Europe, purchased approximately 1.8 million and 732,000 shares at \$6.00 and \$5.94 per share, which represented the closing market price of Palatin shares on the American Stock Exchange on September 7, 2000 and October 2, 2000,

respectively. For every five shares purchased, the investors also received a five-year warrant to purchase one share of common stock at a 25% premium to the closing price. The net proceeds will be used primarily for general corporate purposes, especially for the development and clinical trials of new products based on our proprietary technologies.

On March 15, 2000 we entered into an agreement with Watson Laboratories Inc. (f/k/a TheraTech, Inc.) to terminate our License and Development Agreement with Watson dated March 18, 1998. In connection with the termination, we paid Watson approximately \$500,000.

On August 16, 1999, we entered into a strategic collaboration agreement with Mallinckrodt, Inc., a large international healthcare products company, to jointly develop and market LeuTech. In October 2000, Tyco International, Ltd. acquired Mallinckrodt. Under the terms of this agreement, we received \$500,000 in connection with a licensing fee; \$13 million pursuant to the issuance of 700,000 shares of Series C convertible preferred stock; and approximately \$5.6 million from shared development costs of LeuTech. We are currently negotiating an amendment to the agreement with Mallinckrodt to provide for, among other things, additional funding by Mallinckrodt, amending the reimbursement and expense sharing provisions and payment schedules, as well as providing Mallinckrodt with additional rights.

22

#### Table of Contents

During 2001, we entered into an agreement to lease a new facility of approximately 28,000 square feet in Cranbury, New Jersey that will combine both the research and development facility in Edison, New Jersey and the corporate offices in Princeton, New Jersey. The lease is subject to our approval of certain conditions of the lease and would expire 10 years from commencement. Subject to our acceptance or renegotiation of these conditions, we would anticipate occupying the new space in the first quarter of calendar year 2002. Should we be unable to negotiate acceptable final terms, we could terminate the agreement. Our anticipated cash outlay related to the move is projected at \$1.6 million.

As of April 2000, we entered into an amendment to our research and development facility lease, which increased our rentable space from approximately 10,500 square feet to approximately 15,800. Our aggregate future annual minimum lease payments escalate from approximately \$203,000 until July 13, 2002 to \$300,000 from July 14, 2002 through July 13, 2007.

As of December 7, 1999, we entered into a five-year lease on administrative offices in Princeton, New Jersey. Minimum future lease payments range from approximately \$187,000 in year one to approximately \$202,000 in year five. We have entered into a sublease agreement with Derma Sciences, Inc. on our previous administrative offices. Under the sublease agreement Derma reimburses us 100% of all rents and utility charges.

In March 1997, we entered into a ten-year lease on research and development facilities in Edison, New Jersey, which commenced August 1, 1997. Minimum annual future lease payments escalate from approximately \$116,000 per year to \$200,000 per year after the fifth year of the lease term. The lease will expire in fiscal year 2007.

We have three license agreements that require minimum yearly payments. Future minimum payments under the license agreements are: 2002 - \$300,000, 2003 - \$300,000, 2004 - \$200,000, 2005 - \$200,000 and 2006 - \$200,000.

We are and expect to continue actively searching for certain products and technologies to license or acquire, now or in the future. If we are successful in identifying a product or technology for acquisition, we may require substantial funds for such an acquisition and subsequent development or commercialization. We do not know whether any acquisition will be consummated in the future.

We have incurred negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. We plan to continue to refine our operations, control expenses, evaluate alternative methods to conduct our business and seek available and attractive sources of financing and sharing of development costs through strategic collaboration agreements or other resources. We believe that through one or a combination of such factors, we will obtain adequate financing to fund our operations through fiscal year 2002, based on current expenditure levels. Should appropriate sources of financing not be available, we would delay certain clinical

23

#### Table of Contents

trials and research activities until such time as appropriate financing was available. There can be no assurance that our financing efforts will be successful.

We anticipate incurring additional losses over at least the next several years, and we expect our losses to increase as we expand our research and development activities relating to LeuTech, PT-141 and our MIDAS technology. To achieve profitability, we, alone or with others, must successfully develop and commercialize our technologies and proposed products, conduct pre-clinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and we do not know whether we will be able to achieve profitability on a sustained basis, if at all.

#### **Factors Affecting our Business Condition**

In addition to the other information included in this report, the following factors should be considered in evaluating our business and future prospects:

# We expect to continue to incur substantial losses over the next several years and we may never become profitable.

We have never been profitable and we may never become profitable. As of June 30, 2001, we had an accumulated deficit of \$54,105,039 and a loss for the year then ended of \$10,599,237. We anticipate substantial losses over the next few years associated with the manufacturing and marketing of LeuTech, and continued research and development of PT-141 and MIDAS. In addition, Mallinckrodt Inc., which has provided substantial funding for LeuTech development since August 1999, was acquired by Tyco International, Ltd. in October 2000. Although we are currently negotiating an amendment to the collaboration agreement with Tyco/Mallinckrodt, we do not know whether additional funding will be provided or that expenses will continue to be shared. If additional funding is not provided or obtained, our losses will continue to accumulate. There can be no assurance that additional funds will be available when needed, or on terms acceptable to us. If we are unable to obtain additional financing as needed, we may be required to reduce the scope of our operations, which will have a material adverse effect on our business.

# Development and commercialization of our proposed products and technologies involves a lengthy, complex and costly process and we may never develop or commercialize any products.

Our proposed products are at various stages of research and development and may never be successfully developed or commercialized. We will need regulatory approval to market LeuTech for diagnosis of appendicitis, and we are still conducting clinical trials on the use of LeuTech for other indications. PT-141 and MIDAS will require significant further research, development and testing. You should evaluate Palatin in light of the uncertainties, delays,

#### Table of Contents

difficulties and expenses commonly experienced by early stage pharmaceutical companies, which may include unanticipated problems and additional costs relating to:

0	the development and testing of products in animals and humans;
0	product approval or clearance;
0 0	regulatory compliance; good manufacturing practices;
0	product introduction; and

o marketing and competition.

# We could lose our rights to LeuTech and PT-141, which would adversely affect our potential revenues.

Our rights to a key antibody used in LeuTech are dependent upon an exclusive license agreement with The Wistar Institute of Biology and Anatomy. Our rights to PT-141 are dependent upon an exclusive license agreement with Competitive Technologies, Inc. These agreements contain specific performance criteria and require us to pay royalties and make milestone payments. Failure to meet these requirements, or any other event of default under the license agreements, could lead to termination of the license agreements. If a license agreement is terminated we may be unable to make or market the covered product, in which case we may lose the value of our substantial investment in developing the product, as well as any future revenues from selling the product.

# The FDA may not approve the marketing of LeuTech, which would adversely affect our potential revenues.

We completed clinical trials of LeuTech for the diagnosis of equivocal appendicitis in the spring of 1999. In November 1999, we filed an application with the FDA for approval to market LeuTech for that indication. The FDA has done a complete review of our LeuTech application and on September 23, 2000 sent us a complete review letter requesting additional data on LeuTech manufacturing, product development and process validation. The FDA will not take any further action on our application until we provide the requested information. We are currently in the process of obtaining the data requested by the FDA. This process is uncertain, costly and could require substantial time. If we are able to obtain the requested manufacturing, product development and validation data, we will provide it to the FDA as an amendment to our marketing application. FDA review of the application amendment can be a long and uncertain process. The amendment must demonstrate that we have satisfactorily addressed all of the issues contained in the complete review letter, before the FDA can approve LeuTech for commercial use. We will need to rely on our contract manufacturers to obtain a substantial part of the requested application. We cannot know for certain whether we can provide the requested

25

#### Table of Contents

information, how long it will take, or whether the data we provide will be satisfactory to the FDA. Failure to obtain regulatory approval of LeuTech, or delays in obtaining regulatory approval of LeuTech, would eliminate or delay our potential revenues from sales of LeuTech. This could make it more difficult to attract investment capital for funding our other research and development projects.

#### Production and supply of LeuTech depends on contract manufacturers over whom we have no control.

We do not have the facilities to manufacture LeuTech. We depend on Dutch State Mines of the Netherlands for the manufacture of the antibody used in LeuTech, and on Ben Venue Laboratories of Cleveland, Ohio for the manufacture of LeuTech kits. Our contract manufacturers must perform LeuTech manufacturing activities in a manner that complies with FDA regulations. Failure to conduct their activities in compliance with FDA regulations could negatively impact our ability to receive FDA approval of LeuTech. The failure of either of these manufacturers to supply these key components of LeuTech, or their inability to comply with FDA manufacturing regulations, could force us to seek other manufacturers and could interfere with our ability to deliver product. Establishing relationships with new suppliers, any of whom must be FDA-approved, is a time-consuming and costly process.

# We have limited experience in marketing, distributing and selling diagnostic imaging products and will rely on our marketing partner to provide these capabilities.

If the FDA approves LeuTech for marketing, we will depend on our arrangement with Tyco Healthcare, a division of Tyco International, Ltd., to market, sell and distribute LeuTech. Tyco Healthcare is our exclusive marketing, sale and distribution partner for LeuTech. If Tyco Healthcare fails to market LeuTech, our potential revenues from the sale of LeuTech will be adversely affected. If the arrangement with Tyco Healthcare fails, we may have difficulty establishing new marketing relationships, and in any event, we will have limited control over these activities.

#### If LeuTech does not achieve market acceptance, our business will suffer.

Approval of LeuTech for marketing and sale does not assure the product's commercial success. LeuTech, if successfully developed, will compete with drugs manufactured and marketed by major pharmaceutical and other biotechnology companies. Physicians, patients or the medical community in general may not accept and utilize LeuTech. Imaging agents such as LeuTech generally take longer to achieve market acceptance following marketing approval than other drugs. The degree of market acceptance of LeuTech will depend on a number of factors, including:

o the establishment and demonstration of the clinical efficacy and safety;

o potential advantage over alternative treatment methods; and

26

#### Table of Contents

o reimbursement policies of government and third-party payors.

If LeuTech does not achieve adequate market acceptance, our business, financial condition and results of operations will be adversely affected.

#### Competing products and technologies may make LeuTech and our other potential products noncompetitive.

We are aware of one company developing an antibody-based product which may compete with LeuTech as to certain indications. The competing product is marketed in some European countries and regulatory approval is pending in the United States. Palatin is also aware of at least one other company developing a peptide-based product which may also compete with LeuTech as to certain indications. In addition, other technologies may also be used to diagnose appendicitis, including computerized tomography or CT scan, and ultrasound technologies.

We are aware that there is already an FDA-approved treatment for erectile dysfunction. This product is also approved in Europe, Japan and most of the world's pharmaceutical markets. In addition, we are aware of at least three other products treating erectile dysfunction that have been submitted for approval in the United States, Europe and

most of the world's pharmaceutical markets. Potentially, in order to achieve approval and market acceptance, PT-141 may be required to demonstrate efficacy and safety equivalent or superior to these other products.

The pharmaceutical and diagnostic industries are highly competitive. We are likely to encounter significant competition with respect to LeuTech, PT-141 and our other potential products. The intellectual property issues discussed above may affect the extent of competition that we may face. (See "Business of Palatin--Patents and Proprietary Information.") Many of our competitors have substantially greater financial and technological resources than we do. Many of them also have significantly greater experience in research and development, marketing, distribution and sales than we do. Accordingly, our competitors may succeed in developing, marketing, distributing and selling products and underlying technologies more rapidly than us. These competitive products or technologies may be more effective and useful and less costly than LeuTech, PT-141 or our other potential products. In addition, academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and may develop competing products or technologies on their own or through strategic alliances or collaborative arrangements.

# Contamination or injury from hazardous materials used in the development of LeuTech, PT-141 and MIDAS could result in liability exceeding our financial resources.

Our research and development of LeuTech, PT-141 and MIDAS involves the use of hazardous materials and chemicals, including radioactive compounds. We cannot completely eliminate the risk of contamination or injury from these materials. In the event of contamination or injury, we may be responsible for any resulting damages. Damages could be significant and could exceed our financial resources, including the limits of our insurance.

# Our stock price has ranged from \$2.00 to \$8.188 over the last 12 months, and we expect it to remain volatile, which could limit investors ability to sell stock at a profit.

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

27

Table of Contents

0	continued operating losses;
0	announcements of technological innovations or new therapeutic products;
0	announcement or termination of collaborative relationships by us or our competitors;
0	announcements of mergers and acquisitions involving our suppliers and collaborators;
0	FDA approval or disapproval for marketing LeuTech;
0	governmental regulation;
0	clinical trial results;
0	developments in patent or other proprietary rights; and
0	public concern as to the safety of our products

# Trading in our stock over the last 12 months has been limited, so investors may not be able to sell as much stock as they want at prevailing prices.

The average daily trading volume in our common stock was approximately 29,000 shares and the average daily number of transactions was approximately 20 over the last 12 months. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices.

# Our management and principal stockholders together control approximately 34% of our voting securities, a concentration of ownership which could delay or prevent a change in control.

Our executive officers and directors beneficially own approximately 11% of our voting securities and our 5% or greater stockholders beneficially own approximately 23% of our voting securities. These stockholders, acting together, will be able to influence and possibly control most matters submitted for approval by our stockholders, including the election of directors, delaying or preventing a change of control, and the consideration of transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

#### Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk. Our exposure to market risk related to changes in interest rates relates primarily to our investment portfolio. We invest in instruments that meet high credit quality

28

Table of Contents

standards, and we limit the amount of credit exposure as to any one issue, issuer and type of investments.

As of June 30, 2001, our cash and cash equivalents consisted of \$11,456,424, most of which were short term investments having an original maturity of less than three months. Due to the average maturity and conservative nature of our investment portfolio, we do not believe that short term fluctuations in interest rates would materially affect the value of our securities.

29

Table of Contents

Item 8.

#### Table of Contents Consolidated Financial Statements

The following consolidated financial statements of the Company are filed as part of this Report:

	Page
Report of Independent Public Accountants	31
Consolidated Balance Sheets	32
Consolidated Statements of Operations	33
Consolidated Statements of Stockholders' Equity (Deficit)	34

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Consolidated Statements of Cash Flows		39
Notes to Consolidated Financial Statements		41
	30	

Table of Contents (Financial)

#### **REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Palatin Technologies, Inc.:

We have audited the accompanying consolidated balance sheets of Palatin Technologies, Inc. (a Delaware corporation in the development stage) and subsidiaries as of June 30, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended June 30, 2001 and the period from January 28, 1986 (inception) through June 30, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Palatin Technologies, Inc. and subsidiaries as of June 30, 2001 and 2000 and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2001 and the period from January 28, 1986 (inception) through June 30, 2001, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania
September 10, 2001

31

Table of Contents (Financial)

# PALATIN TECHNOLOGIES, INC.

(A Development Stage Enterprise) Consolidated Balance Sheets

	June 3	30,
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,456,424	\$ 3,219,5
Short-term investments	_	2,155,6
Accounts receivable	_	953,1

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

Prepaid expenses and other	204,731	179,79
Total current assets	11,661,155	6,508,16
Property and equipment, net	1,924,962	1,573,14
Restricted cash Other	45,017	263,07 541,01
	\$ 14,244,209	\$ 8,885,39
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:	¢ 1 100 CC0	ė 1 010 0 <sup>r</sup>
Accounts payable Accrued expenses	\$ 1,129,660 397,119	۶ 1,012,07 584 83
Accrued compensation	607,286	383,33
Deferred license revenue	166,666	
Total current liabilities	2,300,731	1,980,23
Deferred license revenue	27,778	
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock of \$.01 par value - authorized 10,000,000 shares;		
Series A Convertible; 29,317 and 31,561 shares issued and		
outstanding as of June 30, 2001 and 2000, respectively;	293	31
Series B Convertible; 2,000 shares issued and outstanding		
as of June 30, 2000; Series C Convertible; 700,000 shares issued and outstanding	-	2
as of June 30, 2001 and 2000, respectively;	7,000	7,00
Common stock of \$.01 par value - authorized 75,000,000 shares;		.,
Issued and outstanding 11,199,658 and 7,902,372 shares as of		
June 30, 2001 and 2000 respectively;	111,997	79,02
Additional paid-in capital	65,981,568	50,324,60
Deferred compensation Deficit accumulated during development stage	(80,119) (54,105,039)	(43.505.80
accumutation and my accordphicne beage		
	11,915,700	6,905,16
	\$ 14,244,209	\$ 8,885,39

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

32

Table of Contents (Financial)

PALATIN TECHNOLOGIES, INC. (A Development Stage Enterprise) Consolidated Statements of Operations

	Inception (January 28, 1986)			Year E	Inded June 3
	through June 30, 2001		2001		2000
REVENUES:					
Grants and contracts License fees and royalties Other	\$ 9,543,165 1,900,963 318,917				
Total revenues	11,763,045		,788,092		5,117,111
OPERATING EXPENSES:					
Research and development General and administrative Net intangibles write down	42,856,287 22,377,115 259,334	10, 3,	,108,999 ,024,841 -		9,109,619 4,567,273 -
Total operating expenses	65,492,736				3,676,892
OTHER INCOME (EXPENSES): Interest income Interest expense Merger costs	2,141,564 (1,955,953) (525,000)				
Total other income/(expenses)	(339,389)		782,470		
Loss before income taxes & cumulative effect of accounting change Income tax benefit	(54,069,080) 325,152		,563,278) 325,152		(8,183,438)
Loss before cumulative effect of accounting change	(53,743,928)	(10,	,238,126)		(8,183,438)
Cumulative effect of accounting change (Note	2) (361,111)		(361,111)		_
NET LOSS	(54,105,039)	(10,	,599,237)		(8,183,438)
PREFERRED STOCK DIVIDEND	(3,121,525)		_		-
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(57,226,564)	\$(10,	,599,237)		
Basic and diluted net loss per Common share Basic and diluted net loss before cumulat: effect of accounting change Cumulative effect of accounting change	ive	Ş	(1.01) (0.04)	Ş	(1.10)
Basic and diluted net loss		\$	(1.05)		(1.10)
Weighted average number of Common shares outstanding used in computing basic and diluted net loss per Common share		10,			7,441,082

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

33

Table of Contents (Financial)

#### PALATIN TECHNOLOGIES, INC. (A Development Stage Enterprise) Consolidated Statements of Stockholders' Equity (Deficit)

#### Preferr \_\_\_\_\_ Amount Subs Shares \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \$ – Balance at inception \_ Preferred stock subscriptions \_ \_ \_ Net loss from inception \_ \_\_\_\_ \_\_\_\_\_ Balance, August 31, 1995 \_ Preferred stock subscriptions 4,000 Issuance of Preferred shares 4,000,000 Issuance of Common shares on \$10,395,400 private placement Shares earned but not issued \_ Net loss Balance, June 25, 1996 4,000,000 4,000 (4,000) Conversion to Palatin Technologies, Inc. (4,000,000) Adjusted balance, June 25, 1996 Shares outstanding of Palatin Technologies, Inc. Purchase of treasury stock Net loss \_\_\_\_\_ Balance, June 30, 1996 \_ \_ Issuance of Preferred shares, net of expenses 137,780 1,378 Net loss -\_ \_\_\_\_\_ \_\_\_\_\_ 137,780 Balance, June 30, 1997 1,378 Issuance of Preferred shares, net of expenses 18,875 189 Conversion of Preferred shares into Common shares (49,451) (495)Net loss \_ -\_\_\_\_\_ \_\_\_\_\_ 1,072 Balance, June 30, 1998 107,204 Conversion of Preferred shares into Common shares (51,145) (511) Net loss --

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

Table of Contents (Financial)

#### PALATIN TECHNOLOGIES, INC.

# (A Development Stage Enterprise)

# Consolidated Statements of Stockholders' Equity (Deficit)

- continued -

			Preferr
	Shares	Amount	Sub
Balance, June 30, 1999	56,059		561
Issuance of Preferred shares, net of expenses	700,000	-	7,000
Conversion of Preferred shares into Common shares	(22,498)		(225)
Net loss	_		_
Balance, June 30, 2000	733,561	\$ 7	,336
Conversion of Preferred shares into Common shares	(4,244)		(43)
Net loss	_		_
Balance, June 30, 2000	729,317	\$ 7	,293
=====			

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

35

Table of Contents (Financial)

# PALATIN TECHNOLOGIES, INC.

#### (A Development Stage Enterprise) Consolidated Statements of Stockholders' Equity (Deficit) - continued -

	Shares	Amount		Earned but not Issued		D Com	
Balance at inception		\$ –	\$	\$ –	\$	\$	
Issuance of shares from inception Net loss from inception	6,922,069	1,177,786	100,000	110,833	_	_	
Balance, August 31, 1995 Issuance of Preferred shares Issuance of Common shares on	6,922,069 -	1,177,786	100,000	110,833			
\$10,395,400 private placement Shares earned but not issued	41,581,600	9,139,303	-	_ 266,743	-		
Issuance of Common shares Net loss	1,054,548	458,977			-		
Balance, June 25, 1996	49,558,217	10,776,066		53,030			
Conversion to Palatin Technologies Inc.	(46,807,465)	(10,748,558)	10,752,558	-	_		

Common Stock

),752,558	53,030	_	
(1,082)	-	-	
139,459	_	-	
_	_	(1,667)	
),890,935	53,030	(1,667)	
L,635,653	_	-	
-	250,141	_	
316,761	(303,171)	-	
(1,664)	_	1,667	
1,472,716	-	_	(1
_	_	-	
-	-	-	
- )	139,459 	139,459 - - ,890,935 53,030 ,635,653 - 250,141 316,761 (303,171) (1,664) -	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

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

36

#### Table of Contents (Financial)

#### PALATIN TECHNOLOGIES, INC.

(A Development Stage Enterprise)

#### **Consolidated Statements of Stockholders' Equity (Deficit)**

- continued -

				Common Sto	ock 	
	Shares	Amount	Additional Paid-in Capital	but not	Treasury Stock	L Con
Balance, June 30, 1997	3,020,373	30,204	24,314,401			(1
Issuance of Preferred shares, net of expenses	_	_	1,573,295	_	_	
Issuance of Preferred shares expense recapture	_	-	49,733	_	_	
Issuance of Common shares Issuance of Common shares upon	66,696	666	94,873	_	_	
conversion of Preferred shares Issuance of stock options below		10,126	(9,820)	_	_	
fair market value Amortization of deferred	_	_	1,161,156	_	_	( ]
compensation Net loss		-	-	-	-	
Balance, June 30, 1998	4,099,623	40,995	27,183,638			
Issuance of Common shares Issuance of Common shares upon	1,842,101	18,421	7,594,182	_	_	
conversion of Preferred shares Issuance of Common shares upon	1,115,740	11,158	(10,655)	-	-	
exercise of warrants	9,874	99	18,676	-	-	

# REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

Issuance of Common shares upon exercise of options Issuance of stock options below	70 <b>,</b> 257	703	13,348	_	_	
fair market value	_	_	811,054	_	_	
Amortization of deferred			011,001			
compensation	_	_	_	_	_	1
Net loss	-	-	-	_	_	
Balance, June 30, 1999	7,137,595	71,376	35,610,243			
, , ,	, - ,	,	-			
Issuance of Preferred shares,						
net of expenses	-	-	12,999,058	_	_	
Issuance of Preferred shares	-	-	-	_	_	
Issuance of Common shares upon conversion of Preferred						
shares	572,374	5,724	(5,462)	_	_	
Issuance of Common shares upon						
exercise of warrants	111,551	1,115	451,097	_	-	
Issuance of Common shares upon						
exercise of options	80,852	809	99 <b>,</b> 667	-	-	
Acceleration of options						
previously granted	-	-	1,170,000	-	-	
Amortization of stock based						
compensation	-	-	-	-	_	
Net loss	-	-	-	-	_	

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

37

Table of Contents (Financial)

# PALATIN TECHNOLOGIES, INC.

#### (A Development Stage Enterprise) **Consolidated Statements of Stockholders' Equity (Deficit)** - continued -

Common Stock

	Shares	Amount	Additional Paid-in Capital	but	rned not sued	Treasury Stock	D Com
Balance, June 30, 2000	7,902,372	\$ 79,024	\$50,324,603	\$		\$ –	\$
Issuance of Common shares,							
net of expenses	2,532,369	25,324	13,954,928		-	-	
Issuance of Common shares upon							
conversion of Preferred							
shares	104,886	1,049	(1,006)		-	-	
Issuance of Common shares upon							
exercise of warrants	173,015	1,730	486,736		-	-	
Issuance of Common shares upon							
exercise of options	487,016	4,870	634,883		-	-	
Stock based compensation	-	_	246,109		-	-	
Acceleration of options							
previously granted	-	-	335 <b>,</b> 315		-	-	

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#### REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

Amortization of stock based compensation Net loss	-	-	-	-	
Balance, June 30, 2001	11,199,658 ======	\$ 111,997 ======	\$65,981,568 ======	\$ – ========	\$ \$

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

38

#### Table of Contents (Financial)

#### PALATIN TECHNOLOGIES, INC.

(A Development Stage Enterprise)

**Consolidated Statements of Cash Flows** 

	Inception (January 28, 1986) through		Year Ended	
	June 30, 2001		200	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$(54,105,039)	\$(10,599,237)	\$ (8,18	
Adjustments to reconcile net loss to net cash				
used for operating activities:				
Cumulative effect of accounting change	361,111	361,111		
Depreciation and amortization	1,373,856	288,086	24	
License fee	500,000	-		
Interest expense on note payable	72,691	-		
Accrued interest on long-term financing	796,038	-		
Accrued interest on short-term financing	7,936	-		
Intangibles and equipment write down	278,318	-		
Common stock and notes payable issued for				
expenses	751,038	-		
Settlement with consultant	(28,731)	-		
Deferred revenue	(166,667)	(166,667)		
Acceleration of options previously granted	1,505,315	335,315	1,17	
Stock based compensation	3,610,916	165,990	1	
Changes in certain operating assets and				
liabilities:				
Accounts receivable	_	953,163	(953	
Prepaid expenses and other	(1,185,432)	111,053	(439	
Accounts payable	1,129,660	117,590	(104	
Accrued expenses and other	543,238	36,239	(296	
Net cash used for operating				
activities	(44,555,752)	(8,397,357)	(8,54	
CASH FLOWS FROM INVESTING ACTIVITIES:		0 155 615	/1 = 0.0	
Sale/(Purchases) of short-term investments, net Purchases of property and equipment	(3,173,226)	2,155,617 (629,899)	(1,700)(35	
Net cash provided/(used) for				

Net cash provided/(used) for

#### REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

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investing activities	(3,173,226)	1,525,718	(2,054
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable, related party	302,000	-	
Payments on notes payable, related party	(302,000)	-	
Proceeds from senior bridge notes payable	1,850,000	_	
Payments on senior bridge notes payable Proceeds from notes payable and	(1,850,000)	-	
long-term debt	3,951,327		
Payments on notes payable and			
long-term debt	(1,951,327)	-	
Proceeds from common stock, stock option			
and warrant issuances, net	32,976,743	15,108,470	48
Proceeds from preferred stock, net	24,210,326	_	11,00
Purchase of treasury stock	(1,667)	-	
Net cash provided by financing			
activities	59,185,402	15,108,470	11,48
NET INCREASE (DECREASE) IN CASH			
AND CASH EQUIVALENTS	11,456,424	8,236,831	88
CASH AND CASH EQUIVALENTS, beginning of period	-	3,219,593	2,33
CASH AND CASH EQUIVALENTS, end of period	\$ 11,456,424		\$ 3,21
		============	

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

39

Table of Contents (Financial)

# PALATIN TECHNOLOGIES, INC.

(A Development Stage Enterprise) Consolidated Statements of Cash Flows

	Inception (January 28, 1986)	Year Ende		
	through = June 30, 2001	2001	200	
SUPPLEMENTAL CASH FLOW INFORMATION:				
Cash paid for interest	\$ 632,694	\$ 5,104	\$ 2	
NON-CASH TRANSACTION: Settlement of accounts payable with Equipment	\$ 900 ===================================	\$	- \$ 	
NON-CASH STOCK ACTIVITY: Conversion of loans from employees to Common stock	\$ 74,187	\$      -	- Ş	
Conversion of note payable to Common stock	\$ 16,000	\$ -	======== \$	

# REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

Common stock issued for equipment	\$ 2,327	\$ –	\$
Common stock and warrants issued for expenses (included above)	\$ 915,765	\$ 31,200	\$
Common stock issued for accrued salaries and bonuses	\$ 16,548	\$	\$
Accrued interest payable in Common stock	\$ 679,097	======================================	======================================

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

40

Table of Contents (Financial)

#### PALATIN TECHNOLOGIES, INC. (A Development Stage Enterprise) Notes to Consolidated Financial Statements

#### (1) ORGANIZATION ACTIVITIES:

*Nature of Business* -- Palatin Technologies, Inc. ("Palatin" or the "Company") is a development-stage pharmaceutical company committed to the discovery, development and commercialization of novel therapeutics. The Company's product portfolio includes PT-141, a novel treatment currently in development for erectile dysfunction, and LeuTech(TM), a radioimaging monoclonal antibody for the rapid diagnosis and detection of equivocal appendicitis. Palatin's patented drug discovery platform, MIDAS, streamlines the drug discovery process with an efficient approach to identify lead compounds from protein targets for drugs. The Company's pipeline includes preclinical candidates from its proprietary MIDAS peptide-chemistry.

*Business Risk and Liquidity* - As shown in the accompanying financial statements, the Company incurred substantial net losses of \$10,599,237 for the year ended June 30, 2001 and has a deficit accumulated in the development stage of \$54,105,039 as of June 30, 2001. The Company anticipates incurring additional losses in the future as it continues development of LeuTech and expands clinical trials for other indications and for PT-141, and continues research and development of PT-141 and its MIDAS technology. To achieve profitability, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct pre-clinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and there can be no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

Management plans to continue to refine its operations, control expenses, evaluate alternative methods to conduct its business, and seek available and attractive sources of financing and sharing of development costs through strategic collaboration agreements or other resources. Management believes that through one or a combination of such factors that it will be able to obtain adequate financing to fund the Company's operations through fiscal year 2002, based on current expenditure levels. Should appropriate sources of financing not be available, management would delay certain clinical trials and research activities until such time as appropriate financing was available. There can be no assurance that the Company's efforts will be successful.

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

*Principles of Consolidation* -- The consolidated financial statements include the accounts of Palatin and its wholly owned inactive subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

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

*Cash and cash equivalents* -- Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a maturity of three months or less at the time of purchase. As of June 30, 2001 and 2000, approximately \$613,000 and \$263,000, respectively, of cash was restricted to secure letters of credit for security deposits on leases.

*Short-Term Investments* -- The Company accounts for its investments in accordance with Statement of Financial Accounting Standards No. 115 "Accounting For Certain Investments in Debt and Equity Securities." The Company classifies such investments as available for sale investments and as such all investments are recorded at fair value. The investments consist of certificates of deposit. Unrealized gains and losses are classified as a separate component of stockholders' equity. As of June 30, 2001, all such investments had matured. Realized gains and losses were recorded in the statement of operations in the period that the transaction occurs.

#### Table of Contents (Financial)

*Property and Equipment* -- Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements. Propety and equipment are recorded at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of 5 years for equipment, 7 years for office furniture and over the term of the lease for leasehold improvements. Maintenance and repairs are charged to expense as incurred while expenditures that extend the useful life of an asset are capitalized.

*Impairment of Long-Lived Assets* -- The Company follows Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine recoverability of its long-lived assets, management evaluates the probability that future undiscounted net cash flows, without interest charges, will be less than the carrying amount of the assets. Impairment is measured at fair value. Fair value is determined by an evaluation of available price information at which assets could be bought or sold including quoted market prices, if available, or the present value of the estimated future discounted cash flows based on reasonable and supportable assumptions.

*Revenue Recognition* -- Grant and contract revenues are recognized as the Company provides the services stipulated in the underlying grants and/or contracts based on the time and materials incurred. License revenues are recognized when the license fee is received and the Company has no future performance obligations.

In August 1999, the Company entered into a strategic collaboration agreement with Mallinckrodt, Inc. to jointly develop and market one of its products (see Note 7). Under the terms of the agreement, the Company granted a worldwide license for sales, marketing and distribution and received a nonrefundable licensing fee of \$500,000. The licensing fee was recognized as revenue in the period that such nonrefundable fees were received.

In fiscal 2001, the Company adopted U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements (SAB 101) which requires up-front, nonrefundable license fees to be deferred and recognized over the performance period. The cumulative effect of adopting SAB 101 to this license fee resulted in a one-time, non-cash charge of \$361,111 or \$0.04 per share, which reflects the deferral of the \$500,000 up-front license fee received from Mallinckrodt in August 1999. Under SAB 101, this payment has been recorded as deferred revenue to be recognized as license revenue over the remaining development term of this agreement. For the year ended June 30, 2001, the Company recognized \$166,667 in license revenue that was included in the cumulative effect adjustment as of July 1, 2000. Prior year financial statements have not been restated to apply SAB 101 retroactively; however the following pro forma amounts show the net loss to common stockholders and net loss per share assuming the Company had retroactively applied SAB 101 to the prior years:

	Year Ended June 30		
	2001	2000	1999
Net loss to common stockholders, as reported	\$(10,599,237) =======	\$ (8,183,438)	\$(12,002,384)
Net loss per common share, as reported	\$ (1.05)	\$ (1.10) = ======	\$ (2.02)
Pro forma net loss to common stockholders	\$(10,238,126) ==========	\$ (8,544,549)	\$(12,002,384) ========
Pro forma net loss per common share	\$ (1.01)	\$ (1.15) = ======	\$ (2.02)

*Research and Development Costs* -- The costs of research and development activities are charged to expense as incurred.

*Stock Options* -- The majority of common stock options issued to employees and non-employee directors have been issued at exercise prices greater than, or equal to, their fair market value at the date granted. Accordingly, no value has been assigned to these options. During the current fiscal year the vesting of certain stock options were based upon performance milestones as determined by the Board of Directors. Upon

42

#### Table of Contents (Financial)

achievement of such milestones, the Company charged to expense approximately \$109,000, which represents the difference between the fair market value of the Company's Common Stock in excess of the exercise price of the option on the date the milestone was achieved. In December 2000, the Company accelerated the vesting period of certain options granted to terminated employees. This modification resulted in a charge to expense of approximately \$335,000, representing the difference between the fair market value in excess of the exercise price on the date of the modification. In addition, during the current fiscal year, stock options were granted to non-employees for services. The fair value of these options, pursuant to the Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), as calculated by the Black-Scholes option pricing model, has been recorded as deferred compensation and is being charged to expense over the vesting period of such options.

*Income Taxes* -- The Company and its subsidiaries file consolidated federal and combined state income tax returns. The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS 109"). SFAS 109 requires, among other things, the use of the

liability method in computing deferred income taxes.

The Company provides for deferred income taxes relating to temporary differences in the recognition of income and expense items (primarily relating to depreciation, amortization and certain leases) for financial and tax reporting purposes. Such amounts are measured using current tax laws and regulations in accordance with the provisions of SFAS 109.

In accordance with SFAS 109, the Company has recorded a valuation allowance against the realization of its deferred tax assets. The valuation allowance is based on management s estimates and analysis, which includes tax laws which may limit the Company s ability to utilize its tax loss carry-forwards.

*Net Loss per Common Share* -- The Company applies Statement of Financial Accounting Standards No. 128, "Earnings per Share" ("SFAS 128"). SFAS 128 requires dual presentation of basic and diluted earnings per share ("EPS") for complex capital structures on the face of the statement of operations. Basic EPS is computed by dividing the income (loss) by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution from the exercise or conversion of securities into Common stock, such as stock options. For the years ended June 30, 2001, 2000 and 1999, there were no dilutive effects of stock options or warrants as the Company incurred a net loss in each period. Options and warrants to purchase 6,551,021 shares of Common Stock at prices ranging from \$0.01 to \$360 per share were outstanding at June 30, 2001.

*Fair Value of Financial Instruments* -- Statement of Financial Accounting Standards No. 107 "Disclosures about Fair Value of Financial Instruments" ("SFAS 107"), requires disclosures of fair value information about financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate the value. In cases where quoted market prices are not available, fair values are based on estimates using present value or other valuation techniques. These techniques are significantly affected by the assumptions used, including discount rate and estimates of future cash flows. In that regard, the derived fair value estimates cannot be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instrument. SFAS 107 excludes certain financial instruments and all non-financial instruments from its disclosure requirements. Accordingly, the aggregate fair value amounts presented do not represent the underlying value of the Company.

*Reclassifications* -- Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation.

43

Table of Contents (Financial)

# (3) PROPERTY AND EQUIPMENT:

Property and equipment consists of the following:

	June 30,		
	2001	2000	
Office equipment Laboratory equipment Leasehold improvements	\$ 570,954 959,258 1,587,673	\$ 544,265 449,857 1,493,864	
	3,117,885	2,487,986	
Logg, Accumulated depression			

Less: Accumulated depreciation

and amortization	(1,192,923)	(914,846)
	\$1,924,962	\$1,573,140
	==============	

For the years ended June 30, 2001, 2000 and 1999, depreciation expense was \$278,078, \$238,483 and \$222,617, respectively.

## (4) COMMITMENTS AND CONTINGENCIES:

*Leases* -- The Company currently leases two facilities in New Jersey under non-cancelable operating leases. Future minimum lease payments under these two leases are as follows:

Fiscal Year ending June 30,		
2002	Ş	525,000
2003		584,000
2004		588,000
2005		463,000
2006 and thereafter		746,000
		,906,000
	==	

For the years ended June 30, 2001, 2000 and 1999, rent expense was \$560,476, \$357,362 and \$261,097, respectively.

During 2001, the Company entered into an agreement to lease a new facility in Cranbury, New Jersey that will combine both the research and development facility in Edison, New Jersey and the corporate offices in Princeton, New Jersey. The lease is subject to the Company's approval of certain conditions of the lease and would expire 10 years from commencement. Subject to the Company's acceptance or renegotiation of these conditions, the Company would anticipate occupying the new space in the first quarter of calendar year 2002. Should the Company be unable to negotiate acceptable final terms, the agreement could be terminated by the Company. In connection with this proposed move, certain of the Company's existing leasehold improvements at its Edison, New Jersey would be impaired. This impairment would result in a non-cash charge of approximately \$900,000 in the first quarter of the fiscal year ending June 30, 2002.

*Employment Agreements* - On July 17, 2001, the Company executed an employment agreement with Perry B. Molinoff, M.D. effective May 1, 2001 and commencing on September 4, 2001. The agreement expires on the second anniversary of the commencement date, provided, however, that on the second anniversary of the commencement date and on each anniversary thereafter, such period shall be automatically extended for additional one-year periods. Pursuant to the agreement, Dr. Molinoff is serving as an executive vice president of the Company in charge of research and development. Under the agreement, Dr. Molinoff was granted options to purchase 245,000 shares of the Company's Common Stock at an exercise price of \$3.39. These options vest

Table of Contents (Financial)

over the next three anniversaries of the commencement date. The agreement includes specific termination pay and vesting of stock options under certain termination events.

On December 13, 2000, the Company entered into a separation agreement with Charles L. Putnam, who resigned as executive vice president, director and chief operating officer effective November 30, 2000. Pursuant to the agreement, Mr. Putnam's previously granted options became fully vested with an expiration date of November 30, 2004. The agreement further provides for benefits as follows:

- o \$250,000 payable in 24 equal semi-monthly installments of \$10,416.67 commencing on the effective date, less benefit deductions, tax withholding and other deductions required by law.
- o Payment by the Company of premiums necessary for the continuation of current group health insurance coverage under the Federal Law called COBRA for 12 months.

Effective May 15, 2001, due to an alleged breach, the Company suspended all payments and benefits. Mr. Putnam has initiated legal action against the Company. Management believes that the Company has good and meritorious defenses to the action and the Company intends vigorously to defend the action.

On June 13, 2000, the Company entered into a separation agreement with Edward J. Quilty, who resigned as president, chairman and chief executive officer on that date. Pursuant to the agreement, Mr. Quilty's previously granted options become fully vested with an expiration date of June 13, 2004. The agreement further provides for benefits as follows:

- o \$400,000 payable in 24 equal monthly installments of \$16,666.66 less benefit deductions, tax withholding and other deductions required by law.
- o Payment by the Company of premiums necessary for the continuation of current group health insurance coverage under the Federal Law called COBRA for 18 months.
- o Continuation of life and disability insurance substantially similar to that which Mr. Quilty was receiving immediately prior to such resignation for 24 months.

The statement of operations for the year ended June 30, 2000 reflects \$1,073,500 of expense, relating to the option acceleration and the above separation agreement.

On June 13, 2000, the Board of Directors of the Company appointed Carl Spana, Ph.D. as president and chief executive officer of the Company. The Board of Directors also named John K.A. Prendergast to serve as Chairman of the Board of Directors, at a compensation of \$116,000 per year.

On October 12, 1998, the Board of Directors ratified employment agreements with three officers of the Company, Carl Spana, Ph.D, Stephen T. Wills and Charles Putnam effective September 11, 1998. Except for Mr. Putnam, pursuant to the agreements, each is serving as an Executive Vice President of the Company. The agreements expired in September 2001 and currently new contracts for Carl Spana, Ph.D. and Stephen T. Wills are being negotiated. Pursuant to the agreements, each officer was granted options to purchase 50,000 shares of the Company s Common Stock at an exercise price of \$2.50, the closing price of the Company s Common Stock on September 11, 1998. These options vest over a two-year period with the first 33% vested immediately, the next 33% vested on the first anniversary of the date of grant and the remaining 34% vested on the second anniversary of the date of grant. The agreements included specified termination pay and vesting of stock options under certain termination events.

*License Agreements* -- The Company has three license agreements that require minimum yearly payments. Future minimum payments under the license agreements are: 2002 - \$300,000, 2003 - \$300,000, 2004 - \$200,000, 2005 - \$200,000 and 2006 - \$200,000.

On March 15, 2000 the Company entered into an agreement with Watson Laboratories Inc. (f/k/a TheraTech, Inc.) to terminate a license and development agreement with Watson dated March 18, 1998. In connection with the termination, the Company paid Watson approximately \$500,000.

### Table of Contents (Financial)

*Legal Proceedings* - The Company is subject to various claims and litigation in the ordinary course of its business. Management believes that the outcome of such legal proceedings will not have a material adverse effect on the Company.

On March 14, 2000, the Company announced that it would not be extending the merger closing date of March 31, 2000 for its previously announced proposed merger with San Diego-based Molecular Biosystems, Inc. and would not be proceeding with the merger. The Company's decision not to proceed with the merger was based on management's view that the merger was not in the best interests of the Company's stockholders.

On or about April 28, 2000, Molecular Biosystems commenced a legal action against the Company and against Evergreen Merger Corporation, a wholly owned subsidiary or the Company, in the Superior Court of the State of Delaware, County of New Castle. In the complaint, Molecular Biosystems seeks damages against the Company and Evergreen arising from the alleged improper termination of the merger agreement dated November 11, 1999, among Molecular Biosystems, the Company and Evergreen. Under the merger agreement, Evergreen would have merged with and into Molecular Biosystems, which would have become a wholly-owned subsidiary of the Company.

As a consequence of the claims alleged in the complaint, Molecular Biosystems contends that it is entitled to an award of damages against the Company and Evergreen in amounts to be determined at trial, but in any event, at least equal to \$1,765,305. This figure represents the amount of a "breakup fee" of \$1,000,000 provided for in the agreement and \$765,305 for the purported costs and expenses allegedly incurred by Molecular Biosystems in connection with the proposed merger. In addition, Molecular Biosystems seeks consequential damages in an unstated amount plus interest and Molecular Biosystems' costs and expenses of the action.

In the Company's response filed in June of 2000, the Company has denied the material allegations. Management believes that the Company has good and meritorious defenses to the action and the Company intends vigorously to defend the action. On January 3, 2001, Alliance Pharmaceutical Corp. (NASDAQ: ALLP) announced that it had completed its acquisition of Molecular Biosystems. This litigation is currently in the discovery and deposition phase.

# (5) STOCKHOLDERS' EQUITY (DEFICIT):

Series C Preferred Offering -- As of August 16, 1999, pursuant to the strategic collaboration agreement with Mallinckrodt (see Note 7), the Company sold 700,000 restricted shares of Series C Convertible Preferred Stock for \$13,000,000. The Series C stock is convertible into 700,000 shares of Common Stock with certain registration and anti-dilution rights, upon the occurrence of the earlier of five years or the occurrence of a change in control of the Company (as defined in the agreement).

*Series B Preferred Offering* -- As of April 28, 1998, the Company completed a private placement of 18,875 shares of Series B Convertible Preferred Stock at a price per share of \$100. The net proceeds to the Company were approximately \$1,600,000, after deducting the finder's fee and other expenses of the Series B Preferred Offering. The Series B Convertible Preferred Stock has been converted into 56,818 shares of Common Stock.

*Series A Preferred Offering* -- On December 2, 1996, the Company commenced the Series A Preferred Offering of units at a price of \$100,000 per unit, each unit consisting of 1,000 shares of Series A Convertible Preferred Stock.

The final closing on the Series A Preferred Offering was effective as of May 9, 1997, with the Company having sold an aggregate total of 137.78 units, representing 137,780 shares of Series A Convertible Preferred Stock, for net proceeds to the Company of approximately \$11,637,000, after deducting commission and other expenses of the Series A Preferred Offering.

Each share of Series A Convertible Preferred Stock is convertible at any time, at the option of the holder, into the number of shares of Common Stock equal to \$100 divided by the Series A Conversion Price . The current Series A Conversion Price is \$4.67, so each share of Series A Convertible Preferred Stock is currently convertible into approximately 21.4 shares of Common Stock. The Series A Conversion Price is

46

### Table of Contents (Financial)

subject to adjustment, under certain circumstances, upon the sale or issuance of Common Stock for consideration per share less than either (i) the Conversion Price in effect on the date of such sale or issuance, or (ii) the market price of the Common Stock as of the date of such sale or issuance. The Conversion Price is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which will result in an increase or decrease in the number of shares of Common Stock outstanding.

*Common Stock Transactions* - In a private placement of Common Stock and warrants in September and October 2000, the Company sold 2,532,368 shares of its Common Stock to a total of nine investors in two tranches: 1,800,000 shares at \$6.00 per share and 732,368 shares at \$5.94 per share for total net proceeds of approximately \$14 million. For every five shares purchased, the investors received an immediately exercisable five-year warrant to purchase one share of Common Stock at 125% of the closing price. As a result, the Company issued warrants to purchase 360,000 shares at an exercise price of \$7.50 per share and warrants to purchase 146,472 shares at an exercise price of \$7.42 per share.

In connection with the private placement, the Company paid a finder's fee of \$1,060,391 and issued five year warrants to the finder to purchase 216,000 shares of Common Stock at \$6.60 per share and 87,884 shares of Common Stock at \$6.53 per share.

In March 1999, the Company sold in a private placement, an aggregate of 514,215 shares of its Common Stock and 565,629 detachable five-year non-redeemable warrants. Each Warrant is exercisable for one share of Common Stock at an exercise price equal to the per share Common Stock purchase price. The Common Stock purchase price, which was based on the average closing bid price for the five business days immediately prior to the respective closing dates, ranged from \$4.48 per share to \$5.06 per share. The Company received net proceeds of approximately \$2,175,000, which was used for working capital and research and development programs.

In connection with the private placement, the Company paid compensation to third parties consisting of an aggregate of approximately \$222,000 in cash and agreed to issue five-year warrants to purchase an aggregate of 114,073 shares of Common Stock at not less than the exercise prices of the warrants sold in the private placement.

In February 1999, the Company sold in a private placement 651,750 shares of its Common Stock, at \$4.00 per share and 651,750 detachable five-year non-redeemable warrants. Each Warrant is exercisable for one share of Common Stock at an exercise price of \$4.70. The Company received net proceeds of approximately \$2,350,000, which was used for working capital and research and development programs.

In connection with the private placement, the Company paid compensation to third parties consisting of an aggregate of approximately \$248,000 in cash and agreed to issue five-year warrants to purchase an aggregate of 194,600 shares of Common stock at \$4.70.

On December 31, 1998, the Company sold in a private placement 287,500 shares of its Common Stock, at \$4.00 per share and 287,500 detachable five-year non-redeemable warrants. Each Warrant is exercisable for one share of Common Stock at an exercise price of \$4.375 per share. The Company received net proceeds of approximately \$1,000,000, which was used for working capital and research and development programs.

In connection with the private placement, the Company paid compensation to third parties consisting of an aggregate of \$92,000 in cash and agreed to issue five-year warrants to purchase an aggregate of 60,000 shares of Common stock at prices ranging from \$3.75 to \$4.375.

On July 8, 1998, the Company sold TheraTech 363,636 shares of Common stock at a sale price of \$5.50 per share or \$2,000,000. The net proceeds of the offering, approximately \$1,964,000, were used for research and development of the dosage form of PT-14, the Company's peptide hormone product for the treatment of male erectile dysfunction.

In the fiscal year ended June 30, 1999, the Company issued 25,000 shares of Common Stock in exchange for services and recorded compensation expense for the fair market value of \$5.094 per share.

47

Table of Contents (Financial)

Outstanding Stock Purchase Warrants -- At June 30, 2001, the Company had the following warrants outstanding.

	Common Stock Shares	Exercise Price per Share	Latest Termination Date
	48,387	\$ .22	9/13/05
	26,751	2.64	2/15/06
	2,334	5.43	2/15/06
	212,329	5.43	6/25/06
	69,124	8.68	6/24/02
	278,958	5.137	11/9/02
	978,850	4.375 - 4.70	12/31/03
	679,702	4.48 - 5.57	3/12/04
	22,000	.01	3/15/05
	576,000	6.60 - 7.50	10/05/05
	234,359	6.53 - 7.422	11/20/05
	5,000	7.00	6/05/05
	15,000	4.00	12/15/10
	17,052	6.45 - 6.56	5/9/02
Total	3,165,846	\$ .01 - \$8.68	
	=========	===============	

In December 2000, the Company issued warrants to purchase 15,000 shares of its Common Stock at \$4.00 per share to the Wistar Institute of Anatomy and Biology, as part of the consideration for an agreement with Wistar to amend a technology license which Wistar previously granted to the Company. The warrants expire on December 15, 2010. The fair value of these warrants, of approximately \$31,000 pursuant to SFAS No. 123 as calculated by the Black-Scholes option pricing model, has been charged to expense in the statement of operations.

*Stock Option Plans* -- The Company has one stock option plan currently in effect under which future grants may be issued, the 1996 Stock Option Plan, as amended, approved by the Company's stockholders on November 15, 2000, for which 5,000,000 shares of Common Stock are reserved. The Company has also granted options under agreements with individuals, and not under any plan. On March 24, 1998 the Company's stockholders approved options to two

executive officers to purchase a total of 148,392 shares of Common Stock at an exercise price of \$1.00 per share, which options replaced previously granted options to purchase the same number of shares at an exercise price of \$5.42 per share.

The Company applies disclosures required by SFAS 123. Had compensation cost for the Company's stock option plans been determined based upon the fair value at the grant date for awards under SFAS 123, the Company's net loss and basic and diluted net loss attributable to common stockholders per share for the year ended June 30, 2001 would have been \$12,208,350 and \$1.21 respectively. Net loss and basic and diluted net loss attributable to common stockholders per share for the year ended June 30, 2000 would have been \$10,438,724 and \$1.40, respectively, while net loss and basic and diluted net loss attributable to common stockholders per share for the year ended June 30, 1999 would have been \$12,883,151 and \$2.17, respectively. Because the SFAS 123 method of accounting has not been applied to options granted prior to September 1, 1995, the resulting pro forma compensation cost, and thus pro forma net loss, may not be representative of that to be expected in future years. The weighted average fair market value at the date of grant for options granted during 2001, 2000 and 1999 is estimated as \$2.93, \$2.41 and \$1.29 per share, respectively, using the Black-Scholes option-pricing model. The assumptions used in the Black-Scholes model are as follows: dividend yield of 0%, expected

48

#### Table of Contents (Financial)

volatility of 60%, weighted average risk-free interest rate of 5.78% in 2001, 6.47% in 2000 and 4.66% in 1999, and an expected option life of 7 years.

The status of the plans and individual agreements, including predecessor and replacement plans under which options remain outstanding, during the three years ended June 30, 2001, was as follows:

	Number of shares subject to options	per share	Prices per share
Outstanding at June 30, 1998	1,144,136		\$ 6.92
Granted Expired or canceled Exercised	(38,559) (70,257)	\$2.50 - \$5.813 \$.22 - \$360.00 \$.22	
Outstanding at June 30, 1999		\$.20 - \$360.00	\$ 4.26
Granted Expired or canceled Exercised	(124,264) (80,854)	\$.20 - \$6.625 \$2.50 - \$10.85 \$.22 - \$6.25	
Outstanding at June 30, 2000	3,008,500	\$.20 - \$360.00	\$3.92
Granted Expired or canceled Exercised	(119,434) (487,016)	\$2.86 - \$6.063 \$3.50 - \$6.00 \$.20 - \$3.875	
Outstanding at June 30, 2001	3,385,175	\$.22 - \$360.00	\$4.14
Exercisable at June 30, 2001		\$.22 - \$360.00	===== \$4.27 =====

## (6) INCOME TAXES:

The Company has had no income tax expense or benefit since inception because of operating losses. Deferred tax assets and liabilities are determined based on the estimated future tax effect of differences between the financial statements and tax reporting basis of assets and liabilities, given the provisions of the tax laws. Based on the Company's historical losses, a valuation allowance for the net deferred tax assets has been recorded at June 30, 2001.

The Tax Reform Act of 1986 imposes limitations on the use of net operating loss carryforwards if certain stock ownership changes occur. As a result of past changes in majority ownership, the Company most likely will not be able to fully realize the benefit of its net operating loss carryforwards.

Significant components of the Palatin's deferred tax asset for federal and state purposes is as follows:

		June 30
	2001	2000
Net operating loss carryforwards Research and development tax credits Non-deductible expenses	\$17,820,000 716,000 780,000	\$14,855,000 551,000 276,000
Valuation Allowances	19,316,000 (19,316,000)	15,682,000 (15,682,000
Net deferred tax assets	\$ –	\$ – =======

A valuation allowance was established for 100% of the deferred tax assets as realization of such benefits is not assured.

During 2001, the Company sold New Jersey State operating loss carryforwards and research and development credits, which resulted in the recognition of a \$325,152 tax benefit.

Table of Contents (Financial)	

# (7) GRANTS AND CONTRACTS:

The Company applies for and has received grants and contracts under the Small Business Innovative Research ("SBIR") program and other federally funded grant and contract programs. Since inception, approximately \$3,657,000 of the Company's revenues has been derived from federally or state funded grants and contracts. Under federal grants and contracts, there are no royalties or other forms of repayment; however, in certain limited circumstances the government can acquire rights to technology which is not being commercially exploited.

On August 16, 1999, the Company entered into a Strategic Collaboration Agreement with Mallinckrodt, Inc., a large international healthcare products company, to jointly develop and market LeuTech. In October 2000, Tyco International, Ltd. acquired Mallinckrodt. Under the terms of the agreement, Mallinckrodt paid a \$500,000 license fee (see Note 2) and purchased 700,000 restricted shares of Series C Convertible Preferred Stock for \$13,000,000 (see Note 5). In addition, Mallinckrodt agreed to make milestone payments totaling \$10,000,000 upon FDA approval of the first LeuTech indication and attainment of sales goals following product launch, reimburse the Company for 50% of all ongoing LeuTech development costs and pay the Company a transfer price on each LeuTech product unit and a royalty on Mallinckrodt's future net sales of LeuTech. After offsetting the \$2,000,000 subordinated note to

### 49

Mallinckrodt including interest of \$46, 849, the Company received net proceeds of \$11, 453,151 on August 17, 1999. During the years ended June 30, 2001 and 2000, the Company recognized \$1,400,000 and \$4,150,000 respectively, as contract revenue related to the development costs of LeuTech.

The Company is currently negotiating an amendment to the agreement with Mallinckrodt to provide for, among other things, additional funding by Mallinckrodt, amending the reimbursement and expense sharing provisions and payment schedules, as well as providing Mallinckrodt with additional rights.

## (8) LICENSING FEES AND ROYALTIES:

In December 1996, the Company entered into an Option Agreement with Nihon Medi-Physics ("Nihon"), pursuant to which the Company received, in January 1997, an initial payment of \$1,000,000 before Japanese withholding taxes of \$100,000 (the "Initial Payment"). The Company has accounted for the Initial Payment by recognizing license fee revenue of \$350,000, which represents the non-refundable portion of the Initial Payment, and deferred license fee revenue of \$550,000.

The Company recognized \$550,000 in license fees as revenue during the quarter ended December 31, 1998 related to its license option agreement with Nihon. This \$550,000 was recognized pursuant to a determination by both Nihon and the Company to change the development emphasis and terminate the original agreement. The Company was not required to perform any future services under this agreement.

In May 1997, the Company entered into a License Agreement with The Wistar Institute of Anatomy and Biology (Wistar) related to the antibody and cell line used for LeuTech for a defined field of use. The agreement includes future payments to Wistar based on milestones. The Company paid \$50,000 in license fees during the year ended June 30, 1999, such fee was accounted for as an expense in the statement of operations during the year ended June 30, 1999.

On March 18, 1998, the Company entered into a License and Development Agreement with TheraTech, Inc. (TheraTech) pursuant to which the Company paid, in July 1998, \$500,000 to TheraTech as a license fee. Such license fee was accounted for as an expense in the statement of operations during the year ended June 30, 1998. The development agreement includes additional payments to TheraTech related to the joint effort under the product development program.

On March 31, 1998, the Company entered into a License Agreement with Competitive Technologies, Inc. (CTI) pursuant to which the Company paid, in July 1998, \$50,000 to CTI as a license fee. Such license fee was accounted for as an expense in the statement of operations during the year ended June 30, 1998. The agreement includes future payments to CTI in subsequent years based on certain factors. The Company paid

50

Table of Contents (Financial)

\$50,000 in license fees during the year ended June 30, 1999, such fee was accounted for as an expense in the statement of operations during the year ended June 30, 1999.

On August 16, 1999, the Company received an exclusive worldwide license fee of \$500,000 (excluding Europe) for sales, marketing and distribution of LeuTech from Mallinckrodt, Inc. (See Note 7)

# (9) CONSOLIDATED QUARTERLY FINANCIAL DATA -- UNAUDITED:

The following table provides quarterly data for the fiscal years ended June 30, 2001 and 2000.

	Three Months Ended							
			D	ec. 31, 2000	M	ar. 31, 2001		June 30, 2001
		(amount		thousands			hare	data)
Total revenues	\$	897	\$	706	\$	143	\$	42
Total operating expenses		3,162		3,093		3,013		3,865
Total other income (expense)		85		278		264		155
Loss before income taxes and cumulative effect of accounting change								(3,668)
Income tax benefit		-		325		_		_
Loss before cumulative effect of accounting change		(2,180)		(1,784)		(2,606)		(3,668)
Cumulative effect of accounting change		(361)				_		_
Net loss	\$ 	(2,541)		(1,784)		(2,606)		(3,668)
Net loss per share: Basic and diluted net loss before cumulative effect of accounting change Cumulative effect of accounting change		(0.27) (0.04)		(0.17)	\$	(0.24)	\$- 	(0.33) _
Basic and diluted net loss per common share				(0.17)				
Weighted average number of common shares outstanding, used in computing basic and diluted net loss per common share		080,352		<b>,</b> 366 <b>,</b> 170	•		•	•

Amounts for each of the first three quarters of fiscal 2001 have been restated to give effect for the implementation of SAB 101 in the fourth quarter retroactively to July 1, 2000. The impact of the change resulted in an increase in total revenues and corresponding decrease in loss before cumulative effect of change in accounting principle of \$41,667 for each of the quarters ended March 31, December 31, and September 30 as compared to amounts previously reported in Form 10-Q filed with the SEC.

Table of Contents (Financial)

	Three Months Ended							
	Sept. 30, Dec. 1999 19			2000				
		(amour		in thousand				data)
Total revenues	\$	1,750	\$	1,010	\$	1,428	\$	929
Total operating expenses		3,218		3,912		3,342		3,205
Total other income (expense)		46		114		106		110
Net loss	\$	(1,422)	\$	(2,788)	\$	(1,808)	\$	(2,166)
Basic and diluted net loss per common share		(0.20)		(0.38)	\$	(0.24)	\$	(0.28)
Weighted average number of common shares outstanding, used in computing basic and diluted net loss per common share	7,	203,601		7,242,544		7,461,321		,861,652

## Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

52

Table of Contents

# PART III

The information required by Part III of Form 10-K (Item 10 Directors and Executive Officers of the Registrant, Item 11 Executive Compensation, Item 12 Security Ownership of Certain Beneficial Owners and Management and Item 13 Certain Relationships and Transactions) is incorporated by reference from our definitive proxy statement relating to the 2001 Annual Meeting of Stockholders, which we will file with the SEC within 120 days after our June 30, 2001 fiscal year end.

# **PART IV**

# Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K.

# (a) Documents filed as part of the report:

- 1. <u>Financial statements</u>: the following financial statements are filed as a part of this report under Item 8--Financial Statements and Supplementary Data:
  - Report of Independent Public Accountants
  - Consolidated Balance Sheets
  - Consolidated Statements of Operations

- Consolidated Statements of Stockholders' Equity (Deficit)
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements
- 2. <u>Financial statement schedules</u>: none.
- 3. <u>Exhibits</u>: The following exhibits are filed with this report, or incorporated by reference as noted. Exhibits filed with this report are marked with an asterisk (\*). Exhibits which consist of or include a management contract or compensatory plan or arrangement are marked with an obelisk ( ).

No. Description

- 2.01 Agreement and Plan of Merger dated as of November 11, 1999, between Palatin, Molecular Biosystems, Inc. and Evergreen Merger Corporation. Incorporated by reference to Exhibit 99.2 of our current report on Form 8-K dated November 12, 1999, filed with the SEC on November 30, 1999. We agree to furnish supplementally to the SEC upon request a copy of any omitted schedule.
- 3.01 Certificate of incorporation. Incorporated by reference to Exhibit 3.01 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000.

53

#### Table of Contents

- 3.02 Bylaws. Incorporated by reference to Exhibit 3.2 of our Form 10-QSB for the quarter ended December 31, 1997, filed with the SEC on February 13, 1998.
- 10.01 RhoMed Incorporated 1995 Employee Incentive Stock Option Plan. Incorporated by reference to Exhibit 10.04 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.02 1996 Stock Option Plan, as amended effective July 1, 1999. Incorporated by reference to Exhibit 10.02 of our amended annual report on Form 10-KSB/A for the period ended June 30, 1999, filed with the SEC on December 28, 1999.
- 10.03 Carl Spana Stock Option Agreement. Incorporated by reference to Exhibit
  4.15 of our Form S-8 filed with the SEC on June 17, 1998. +
- 10.04 Charles L. Putnam Stock Option Agreement. Incorporated by reference to Exhibit 4.16 of our Form S-8 filed with the SEC on June 17, 1998. +
- 10.05 Executive Officers Stock Option Agreement. Incorporated by reference to Exhibit 4.18 of our Form S-8 filed with the SEC on June 17, 1998. +
- 10.06 Employment Agreement dated as of October 9, 1998, between Palatin Technologies, Inc. and Charles Putnam. Incorporated by reference to Exhibit 10.37 of our quarterly report on Form 10-QSB for the period ended September 30, 1998, filed with the SEC on November 16, 1998. +
- 10.07 Employment Agreement dated as of October 9, 1998, between Palatin Technologies, Inc. and Carl Spana. Incorporated by reference to Exhibit 10.38 of our quarterly report on Form 10-QSB for the period ended September 30, 1998, filed with the SEC on November 16, 1998. +

- 10.08 Employment Agreement dated as of October 9, 1998, between Palatin Technologies, Inc. and Stephen T. Wills. Incorporated by reference to Exhibit 10.39 of our quarterly report on Form 10-QSB for the period ended September 30, 1998, filed with the SEC on November 16, 1998. +
- 10.09 Employment Agreement dated July 9, 1999 between Palatin Technologies, Inc. and Edward J. Quilty. Incorporated by reference to Exhibit 10.09 of our annual report on Form 10-KSB for the period ended June 30, 1999, filed with the SEC on September 28, 1999.+
- 10.10 Form of RhoMed Class A Warrant. Incorporated by reference to Exhibit 10.16 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.

54

#### Table of Contents

- 10.11 Form of Placement Agent Warrant for the RhoMed Class A Offering. Incorporated by reference to Exhibit 10.17 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.12 Form of RhoMed Class B Warrant. Incorporated by reference to Exhibit 10.19 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.13 Form of Placement Agent Warrant for the RhoMed Class B Offering. Incorporated by reference to Exhibit 10.20 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.14 Form of Placement Agent Warrant for the RhoMed common stock offering. Incorporated by reference to Exhibit 10.22 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.15 Form of Placement Agent Warrant for the Series A Convertible Preferred Stock Offering. Incorporated by reference to Exhibit 10.29 of our registration statement on Form S-3, filed with the SEC on November 25, 1997.
- 10.16 Convertible Preferred Stock Purchase Agreement dated as of April 28, 1998, between Palatin and the named purchasers, relating to Series B convertible preferred stock. Incorporated by reference to Exhibit 99.1 of our current report on Form 8-K dated April 28, 1998, filed with the SEC May 8, 1998.
- 10.17 Stock Purchase Agreement dated as of July 6, 1998, between Palatin and TheraTech, Inc. Incorporated by reference to Exhibit 99.1 of our current report on Form 8-K dated July 8, 1998, filed with the SEC on July 9, 1998.
- 10.18 Lease between Carnegie 214 Associates Limited Partnership and Palatin Technologies, Inc. dated May 6, 1997. Incorporated by reference to Exhibit 10.26 of our annual report on Form 10-KSB for the year ended June 30, 1997, filed with the SEC on September 26, 1997.

55

#### Table of Contents

- 10.19 Lease between WHC-Six Real Estate, L.P. and Palatin Technologies, Inc. dated March 13, 1997. Incorporated by reference to Exhibit 10.27 of our Form 10-KSB for the year ended June 30, 1997, filed with the SEC on September 26, 1997.
- 10.20 Consulting Agreement between Palatin and Summercloud Bay, Inc. Incorporated by reference to Exhibit 10.36 of our annual report on Form 10-KSB/A, Amendment No. 1, dated June 30, 1998, filed with the SEC on October 2, 1998. +
- 10.21 Strategic Collaboration Agreement dated as of August 17, 1999, between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.21 of our amended annual report on Form 10-KSB/A for the period ended June 30, 1999, filed with the SEC on December 28, 1999.
- 10.22 Form of warrant and registration rights for the warrant issued in April 2000 with an expiration date of March 15, 2005. Incorporated by reference to Exhibit 10.22 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000.
- 10.23 Separation Agreement dated as of June 13, 2000 between Palatin Technologies, Inc. and Edward J. Quilty. Incorporated by reference to Exhibit 10.23 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000. +
- 10.24 Letter agreement dated as of July 31, 2000 between Palatin Technologies, Inc. and Robert G. Moussa. Incorporated by reference to Exhibit 10.24 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000. +
- 10.25 Letter agreement dated as of July 31, 2000 between Palatin Technologies, Inc. and James T. O'Brien. Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000. +
- 10.26 Form of stock purchase agreement for our September-October 2000 private placement. Incorporated by reference to Exhibit 10.1 of our report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000.
- 10.27 Form of registration rights agreement for the September-October 2000 private placement. Incorporated by reference to Exhibit 10.2 of the registrant's report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000.
- 10.28 Form of warrant issued to purchasers in the September-October 2000 private placement. Incorporated by reference to Exhibit 10.3 of the registrant's report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000.
- 10.29 Separation Agreement and General Release between Palatin and Charles
   Putnam, dated as of November 30, 2000. Incorporated by reference to Exhibit
   10.1 of our report on Form 10-Q for the quarter ended December 31, 2000,
   filed on February 14, 2001. +

- 10.30 Employment Agreement dated as of July 17, 2001, between Palatin Technologies, Inc. and Perry B. Molinoff. + \*
- 21 Subsidiaries of the registrant. \*
- 23.01 Consent of Arthur Andersen LLP, Independent Auditors, with respect to the financial statements of Palatin. \*

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* Exhibit filed with this report.
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+ Management contract

56

Table of Contents

## (b) Reports on Form 8-K

During the last quarter of the fiscal year ended June 30, 2001, we filed the following reports on Form 8-K: one report, under Item 5, dated May 2, 2001, relating to the progress on our product development programs and to report our third quarter 2001 results of operations. One report, under Item 9, dated June 1, 2001 to announce the plan to hold a teleconference originally scheduled for June 5, 2001. One report, under Item 9, dated June 4, 2001 to announce the rescheduling of the June 5, 2001 teleconference to June 7, 2001.

57

Table of Contents

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

## PALATIN TECHNOLOGIES, INC.

By: <u>/s/ Carl Spana</u> Carl Spana, Ph.D. President and Chief Executive Officer

Date: September 28, 2001

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Carl Spana</u> Carl Spana	President, Chief Executive Officer and Director (principal executive officer)	September 28, 2001
<u>/s/ Stephen T. Wills</u> Stephen T. Wills	Executive Vice President and Chief Financial Officer (principal financial and accounting officer)	September 28, 2001
<u>/s/ John K.A. Prendergast</u> John K.A. Prendergast	Chairman and Director	September 28, 2001
/s/ Robert K. deVeer, Jr.	Director	September 28, 2001

Robert K. deVeer, Jr.

<u>/s/ Kevin S. Flannery</u> Kevin S. Flannery	Director	September 28, 2001
	58	
Table of Contents		
<u>/s/ Zola P. Horovitz</u> Zola P. Horovitz	Director	September 28, 2001
<u>/s/ Robert I. Taber</u> Robert I. Taber	Director	September 28, 2001
	59	
Table of Contents		
	EXHIBIT INDEX	

- 2.01 Agreement and Plan of Merger dated as of November 11, 1999, between Palatin, Molecular Biosystems, Inc. and Evergreen Merger Corporation. Incorporated by reference to Exhibit 99.2 of our current report on Form 8-K dated November 12, 1999, filed with the SEC on November 30, 1999. We agree to furnish supplementally to the SEC upon request a copy of any omitted schedule.
- 3.01 Certificate of incorporation. Incorporated by reference to Exhibit 3.01 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000.
- 3.02 Bylaws. Incorporated by reference to Exhibit 3.2 of our Form 10-QSB for the quarter ended December 31, 1997, filed with the SEC on February 13, 1998.
- 10.01 RhoMed Incorporated 1995 Employee Incentive Stock Option Plan. Incorporated by reference to Exhibit 10.04 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.02 1996 Stock Option Plan, as amended effective July 1, 1999. Incorporated by reference to Exhibit 10.02 of our amended annual report on Form 10-KSB/A for the period ended June 30, 1999, filed with the SEC on December 28, 1999.
- 10.03 Carl Spana Stock Option Agreement. Incorporated by reference to Exhibit
  4.15 of our Form S-8 filed with the SEC on June 17, 1998. +
- 10.04 Charles L. Putnam Stock Option Agreement. Incorporated by reference to Exhibit 4.16 of our Form S-8 filed with the SEC on June 17, 1998. +
- 10.05 Executive Officers Stock Option Agreement. Incorporated by reference to Exhibit 4.18 of our Form S-8 filed with the SEC on June 17, 1998. +
- 10.06 Employment Agreement dated as of October 9, 1998, between Palatin Technologies, Inc. and Charles Putnam. Incorporated by reference to Exhibit 10.37 of our quarterly report on Form 10-QSB for the period ended September 30, 1998, filed with the SEC on November 16, 1998. +

- 10.07 Employment Agreement dated as of October 9, 1998, between Palatin Technologies, Inc. and Carl Spana. Incorporated by reference to Exhibit 10.38 of our quarterly report on Form 10-QSB for the period ended September 30, 1998, filed with the SEC on November 16, 1998. +
- 10.08 Employment Agreement dated as of October 9, 1998, between Palatin Technologies, Inc. and Stephen T. Wills. Incorporated by reference to Exhibit 10.39 of our quarterly report on Form 10-QSB for the period ended September 30, 1998, filed with the SEC on November 16, 1998. +
- 10.09 Employment Agreement dated July 9, 1999 between Palatin Technologies, Inc. and Edward J. Quilty. Incorporated by reference to Exhibit 10.09 of our annual report on Form 10-KSB for the period ended June 30, 1999, filed with the SEC on September 28, 1999.+
- 10.10 Form of RhoMed Class A Warrant. Incorporated by reference to Exhibit 10.16 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.11 Form of Placement Agent Warrant for the RhoMed Class A Offering. Incorporated by reference to Exhibit 10.17 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.12 Form of RhoMed Class B Warrant. Incorporated by reference to Exhibit 10.19 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.13 Form of Placement Agent Warrant for the RhoMed Class B Offering. Incorporated by reference to Exhibit 10.20 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.14 Form of Placement Agent Warrant for the RhoMed common stock offering. Incorporated by reference to Exhibit 10.22 of our annual report on Form 10-KSB for the period ended June 30, 1996, filed with the SEC on September 27, 1996.
- 10.15 Form of Placement Agent Warrant for the Series A Convertible Preferred Stock Offering. Incorporated by reference to Exhibit 10.29 of our registration statement on Form S-3, filed with the SEC on November 25, 1997.
- 10.16 Convertible Preferred Stock Purchase Agreement dated as of April 28, 1998, between Palatin and the named purchasers, relating to Series B convertible preferred stock. Incorporated by reference to Exhibit 99.1 of our current report on Form 8-K dated April 28, 1998, filed with the SEC May 8, 1998.
- 10.17 Stock Purchase Agreement dated as of July 6, 1998, between Palatin and TheraTech, Inc. Incorporated by reference to Exhibit 99.1 of our current report on Form 8-K dated July 8, 1998, filed with the SEC on July 9, 1998.
- 10.18 Lease between Carnegie 214 Associates Limited Partnership and Palatin Technologies, Inc. dated May 6, 1997. Incorporated by reference to Exhibit 10.26 of our annual report on Form 10-KSB for the year ended June 30, 1997, filed with the SEC on September 26, 1997.
- 10.19 Lease between WHC-Six Real Estate, L.P. and Palatin Technologies, Inc. dated March 13, 1997. Incorporated by reference to Exhibit 10.27 of our Form 10-KSB for the year ended June 30, 1997, filed with the SEC on September 26, 1997.

- 10.20 Consulting Agreement between Palatin and Summercloud Bay, Inc. Incorporated by reference to Exhibit 10.36 of our annual report on Form 10-KSB/A, Amendment No. 1, dated June 30, 1998, filed with the SEC on October 2, 1998. +
- 10.21 Strategic Collaboration Agreement dated as of August 17, 1999, between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.21 of our amended annual report on Form 10-KSB/A for the period ended June 30, 1999, filed with the SEC on December 28, 1999.
- 10.22 Form of warrant and registration rights for the warrant issued in April 2000 with an expiration date of March 15, 2005. Incorporated by reference to Exhibit 10.22 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000.
- 10.23 Separation Agreement dated as of June 13, 2000 between Palatin Technologies, Inc. and Edward J. Quilty. Incorporated by reference to Exhibit 10.23 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000. +
- 10.24 Letter agreement dated as of July 31, 2000 between Palatin Technologies, Inc. and Robert G. Moussa. Incorporated by reference to Exhibit 10.24 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000. +
- 10.25 Letter agreement dated as of July 31, 2000 between Palatin Technologies, Inc. and James T. O'Brien. Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended June 30, 2000, filed with the SEC on September 29, 2000. +
- 10.26 Form of stock purchase agreement for our September-October 2000 private placement. Incorporated by reference to Exhibit 10.1 of our report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000.
- 10.27 Form of registration rights agreement for the September-October 2000 private placement. Incorporated by reference to Exhibit 10.2 of our report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000.
- 10.28 Form of warrant issued to purchasers in the September-October 2000 private placement. Incorporated by reference to Exhibit 10.3 of our report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000.
- 10.29 Separation Agreement and General Release between Palatin and Charles
   Putnam, dated as of November 30, 2000. Incorporated by reference to Exhibit
   10.1 of our report on Form 10-Q for the quarter ended December 31, 2000,
   filed on February 14, 2001. +
- 10.30 Employment Agreement dated as of July 17, 2001, between Palatin Technologies, Inc. and Perry B. Molinoff. + \*
- 21 Subsidiaries of the registrant. \*
- 23.01 Consent of Arthur Andersen LLP, Independent Auditors, with respect to the financial statements of Palatin. \*

<sup>\*</sup> Exhibit filed with this report.

<sup>+</sup> Management contract