

PALATIN TECHNOLOGIES INC
Form 10-Q
November 09, 2006

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2006

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 001-15543

PALATIN TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

95-4078884

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

4C Cedar Brook Drive

Cranbury, New Jersey

(Address of principal executive offices)

08512

(Zip code)

(609) 495-2200

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 1, 2006, 71,125,612 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

PALATIN TECHNOLOGIES, INC.
Table of Contents

	<u>Page</u>
<u>PART I - FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements (Unaudited)</u>	
<u>Consolidated Balance Sheets as of September 30, 2006 and June 30, 2006</u>	2
<u>Consolidated Statements of Operations for the Three Months Ended September 30, 2006 and 2005</u>	3
<u>Consolidated Statements of Cash Flows for the Three Months Ended September 30, 2006 and 2005</u>	4
<u>Notes to Consolidated Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	13
Item 4. <u>Controls and Procedures</u>	13
<u>PART II - OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	14
Item 1A. <u>Risk Factors</u>	14
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	14
Item 3. <u>Defaults Upon Senior Securities</u>	14
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	14
Item 5. <u>Other Information</u>	14
Item 6. <u>Exhibits</u>	14
<u>SIGNATURES</u>	

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

PALATIN TECHNOLOGIES, INC.
Consolidated Balance Sheets
(unaudited)

	September 30, 2006	June 30, 2006
	<u> </u>	<u> </u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,192,331	\$ 28,333,211
Available-for-sale investments	2,338,387	2,330,834
Accounts receivable	919,547	69,591
Prepaid expenses and other current assets	913,838	1,453,650
	<u> </u>	<u> </u>
Total current assets	22,364,103	32,187,286
Property and equipment, net	6,186,379	6,347,705
Restricted cash	475,000	475,000
Other assets	941,175	1,037,296
	<u> </u>	<u> </u>
Total assets	\$ 29,966,657	\$ 40,047,287
	<u> </u>	<u> </u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Capital lease obligations, current portion	\$ 131,582	\$ 86,564
Accounts payable	2,556,398	3,092,962
Accrued expenses	5,202,276	4,466,428
Accrued compensation	131,250	803,900
Deferred revenue, current portion	3,409,496	3,995,575
	<u> </u>	<u> </u>
Total current liabilities	11,431,002	12,445,429
Capital lease obligations, net of current portion	272,419	229,585
Deferred rent, net of current portion	2,244,243	2,358,550
Deferred revenue, net of current portion	5,924,068	6,713,942
	<u> </u>	<u> </u>
Total liabilities	19,871,732	21,747,506
	<u> </u>	<u> </u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value, 10,000,000 shares authorized:		
Series A Convertible; 9,997 shares issued and outstanding as of September 30, 2006 and June 30, 2006	100	100
Common stock, \$.01 par value, 150,000,000 shares authorized, 70,878,521 shares issued and outstanding as of September 30, 2006		

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

and June 30, 2006	708,785	708,785
Additional paid-in capital	178,313,670	178,089,176
Accumulated other comprehensive loss	(47,183)	(54,736)
Accumulated deficit	(168,880,447)	(160,443,544)
	<u>10,094,925</u>	<u>18,299,781</u>
Total stockholders' equity		
	<u>\$ 29,966,657</u>	<u>\$ 40,047,287</u>
Total liabilities and stockholders' equity		

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

Table of Contents

PALATIN TECHNOLOGIES, INC.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,	
	2006	2005
REVENUES:		
Royalties	\$ -	\$ 915,515
Licenses, grants and contracts	4,935,102	4,228,263
	<u>4,935,102</u>	<u>4,228,263</u>
Total revenues	4,935,102	5,143,778
	<u>4,935,102</u>	<u>5,143,778</u>
OPERATING EXPENSES:		
Royalties	-	183,329
Research and development	12,125,252	9,365,368
General and administrative	1,560,922	1,752,533
	<u>13,686,174</u>	<u>11,301,230</u>
Total operating expenses	13,686,174	11,301,230
	<u>13,686,174</u>	<u>11,301,230</u>
Loss from operations	(8,751,072)	(6,157,452)
	<u>(8,751,072)</u>	<u>(6,157,452)</u>
OTHER INCOME (EXPENSE):		
Investment income	324,235	124,222
Interest expense	(10,066)	(2,426)
	<u>314,169</u>	<u>121,796</u>
Total other income, net	314,169	121,796
	<u>314,169</u>	<u>121,796</u>
NET LOSS	<u>\$ (8,436,903)</u>	<u>\$ (6,035,656)</u>
Basic and diluted net loss per common share	<u>\$ (0.12)</u>	<u>\$ (0.11)</u>
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	<u>70,878,521</u>	<u>54,488,412</u>

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

Table of Contents

PALATIN TECHNOLOGIES, INC.
Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended September 30,	
	2006	2005
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (8,436,903)	\$ (6,035,656)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	344,200	303,667
Stock-based compensation	224,494	355,138
Changes in operating assets and liabilities:		
Accounts receivable	(849,956)	4,307,472
Inventories	-	(297,848)
Prepaid expenses and other	635,655	124,218
Accounts payable	(536,564)	(910,486)
Accrued expenses and other	(51,109)	(398,535)
Deferred revenues	(1,375,953)	114,973
	<u>(10,046,136)</u>	<u>(2,437,057)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(61,248)	(201,226)
	<u>(61,248)</u>	<u>(201,226)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on capital lease obligations	(33,496)	(2,723)
Proceeds from issuances of common stock and warrants, net	-	10,005,452
	<u>(33,496)</u>	<u>10,002,729</u>
Net cash (used in) provided by financing activities		
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(10,140,880)	7,364,446
CASH AND CASH EQUIVALENTS, beginning of period	28,333,211	15,720,364
	<u>\$ 18,192,331</u>	<u>\$ 23,084,810</u>
CASH AND CASH EQUIVALENTS, end of period		
SUPPLEMENTAL CASH FLOW INFORMATION:		
Equipment acquired by capital lease	\$ 121,348	\$ -

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

Table of Contents

PALATIN TECHNOLOGIES, INC.
Notes to Consolidated Financial Statements
(unaudited)

(1) ORGANIZATION

Nature of Business Palatin Technologies, Inc. (Palatin or the Company) is a biopharmaceutical company primarily focused on discovering and developing targeted, receptor-specific small molecule and peptide therapeutics, including melanocortin (MC)-based therapeutics. Therapeutics affecting the activity of the MC family of receptors may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, cachexia (extreme wasting, generally secondary to a chronic disease), skin pigmentation and inflammation. The Company is exploring other receptor-specific therapeutics using its patented drug discovery platform, including congestive heart failure therapeutics.

Bremelanotide, an MC receptor agonist and the Company s lead therapeutic drug candidate, is a patented, nasally-administered peptide that is in clinical development for the treatment of both male and female sexual dysfunction, under a collaborative development and marketing agreement with King Pharmaceuticals, Inc. (King), a specialty pharmaceutical company.

The Company has preclinical development programs for the treatment of obesity and congestive heart failure resulting from its MIDAS(TM)technology, the Company s proprietary platform technology to design and synthesize compounds that mimic the activity of peptides.

NeuroSpec is a radiolabeled monoclonal antibody product for imaging and diagnosing infection and is the subject of a strategic collaboration agreement with Tyco Healthcare Mallinckrodt (Mallinckrodt). In December 2005, the Company and Mallinckrodt voluntarily suspended the sales, marketing and distribution of NeuroSpec. All ongoing clinical trials and regulatory approvals of NeuroSpec have been suspended. The Company and Mallinckrodt are evaluating future development and marketing activities involving NeuroSpec.

Key elements of the Company s business strategy include entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of the Company s product candidates under development, expansion of the Company s pipeline through the utilization of its MC expertise and patented drug discovery platform, opportunistic acquisition of synergistic products and technologies and partial funding of the Company s development and discovery programs with the cash flow from collaboration agreements.

Business Risk and Liquidity The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company has an accumulated deficit as of September 30, 2006 and incurred a net loss for the three months ended September 30, 2006. The Company anticipates incurring additional losses in the future as a result of spending on its development programs. To achieve profitability, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct successful 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.

The Company expects that its cash, cash equivalents and available-for-sale investments as of September 30, 2006, together with expected revenue from collaboration and license agreements and other income will be adequate to fund the Company s operations for at least the next twelve months. 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. 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 financing efforts will be successful. If adequate funds are not available, the Company s financial condition will be materially and adversely affected.

Concentrations Concentrations in the Company s assets and operations subject it to certain related risks. Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, available-for-sale investments and accounts receivable. The Company s cash and cash equivalents are primarily invested in one money market fund sponsored by a large financial institution. The Company s periodic accounts receivable balances primarily consist of amounts due from its collaboration partners, including \$664,033 from King and \$77,076 from Mallinckrodt.

Table of Contents

Revenues from King and Mallinckrodt as a percentage of total revenues were as follows:

	Three Months Ended September 30,	
	2006	2005
King	99%	80%
Mallinckrodt	1%	20%

(2) BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnote disclosures required to be presented for complete financial statements. In the opinion of management, these consolidated financial statements contain all adjustments (consisting of normal recurring adjustments) considered necessary to present fairly the Company's financial position as of September 30, 2006, and its results of operations and its cash flows for the three months ended September 30, 2006 and 2005. The results of operations for the three-month period ended September 30, 2006 may not necessarily be indicative of the results of operations expected for the full year, except that the Company expects to incur a significant loss for the fiscal year ending June 30, 2007.

The accompanying consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the fiscal year ended June 30, 2006, filed with the Securities and Exchange Commission (SEC), which includes consolidated financial statements as of June 30, 2006 and 2005 and for each of the fiscal years in the three-year period ended June 30, 2006.

(3) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Use of Estimates The preparation of consolidated financial statements in conformity with U.S. 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 Statements of Cash Flows Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a purchased maturity of less than three months. Restricted cash secures letters of credit for security deposits on leases.

Investments The Company classifies its investments as available-for-sale investments and all such investments are recorded at fair value. Unrealized holding gains and losses, net of the related tax effect, if any, are excluded from earnings and are reported in accumulated other comprehensive loss until realized. Interest and dividends on securities classified as available-for-sale are included in investment income. Gains and losses are recorded in the statement of operations when realized or when unrealized holding losses are determined to be other than temporary, on a specific-identification basis.

Fair Value of Financial Instruments The Company's financial instruments consist primarily of cash and cash equivalents, available-for-sale investments, accounts receivable, accounts payable and capital lease obligations. Management believes that the carrying value of these assets and liabilities are representative of their respective fair values.

Property and Equipment Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements and includes assets acquired under capital leases. Property and equipment are recorded at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets, generally five years for laboratory equipment, seven years for office furniture and equipment and the lesser of the term of the lease or the useful life for leasehold improvements. Amortization of assets acquired under capital leases is included in depreciation. Maintenance and repairs are expensed as incurred while expenditures that extend the useful life of an asset are capitalized.

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Impairment of Long-Lived Assets 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 a long-lived asset, management evaluates whether the estimated future undiscounted net

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Table of Contents

cash flows from the asset, without interest charges, are less than its carrying amount. If impairment is indicated, the long-lived asset would be written down to 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.

Other Assets Other assets and other current assets include certain payments the Company made to licensors in cash and stock as their share of up-front payments received from collaboration partners in connection with the Company's collaboration agreements. The Company has treated these payments as incremental direct costs of the up-front payments, to be charged over the same period as the related deferred revenue, in accordance with guidance contained in the SEC's Staff Accounting Bulletin No. 104 and, by analogy, to paragraph 4 of FASB Technical Bulletin 90-1.

Deferred Rent The Company's operating leases provide for rent increases over the terms of the leases. Deferred rent consists of the difference between periodic rent payments and the amount recognized as rent expense on a straight-line basis for the buildings the Company occupies, as well as the value of tenant allowances for leasehold improvements. Rent expense is being recognized ratably over the life of the leases.

Revenue Recognition Royalty revenues represent amounts earned from Mallinckrodt based on a contractual percentage of Mallinckrodt's net sales of NeutroSpec to customers prior to the suspension of sales and marketing activities. Revenue was recognized by the Company in the period in which Mallinckrodt's net sales occurred, as reported by Mallinckrodt to the Company on a quarterly basis.

Revenue from corporate collaborations and licensing agreements consists of up-front fees, research and development funding, and milestone payments. Non-refundable up-front fees are deferred and amortized to revenue over the related performance period. The Company estimates the performance period as the period in which it performs certain development activities under the applicable agreement. Estimated reimbursements for research and development activities and government grants are recorded in the period that the Company performs the related activities under the terms of the applicable agreements. Revenue resulting from the achievement of milestone events stipulated in the applicable agreements is recognized when the milestone is achieved. Revenue resulting from the achievement of milestone events stipulated in the applicable agreements is recognized when the milestone is achieved, provided that such milestone is substantive in nature. Grant and other 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.

Research and Development Costs The costs of research and development activities are charged to expense as incurred, including the cost of equipment for which there is no alternative future use.

Stock Options The Company accounts for options granted to consultants in accordance with Statement of Financial Accounting Standards (SFAS) 123(R), Share-Based Payment. SFAS 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services and requires that the compensation cost relating to share-based payment transactions be recognized in the financial statements, measured by the fair value of the equity or liability instruments issued, adjusted for estimated forfeitures.

The Company accounts for options granted to consultants in accordance with Emerging Issues Task Force Issue 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. The Company determines the value of stock options utilizing the Black-Scholes option-pricing model.

Compensation costs for fixed awards with pro rata vesting are allocated to periods on the straight-line basis.

Income Taxes The Company and its subsidiary file consolidated federal and separate-company state income tax returns. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with SFAS 109 Accounting for Income Taxes, the Company has recorded a valuation allowance against its deferred tax assets. The valuation allowance is based on management's estimates and analysis, which includes provisions of tax laws that may limit the Company's ability to utilize its net operating loss carryforwards.

Net Loss per Common Share Basic earnings per share (EPS) is computed by dividing net 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 and warrants. As of

7

Table of Contents

September 30, 2006 and 2005, common shares issuable upon conversion of outstanding Series A Convertible Preferred Stock and the exercise of outstanding options and warrants amounted to an aggregate of 16,697,450 and 15,175,188, respectively, and were not included in the computation of Diluted EPS because to do so would have been anti-dilutive for the periods presented.

(4) OTHER COMPREHENSIVE LOSS

Other comprehensive loss consists of the following:

	Three Months Ended September 30,	
	2006	2005
Net loss	\$(8,316,903)	\$(6,035,656)
Unrealized gain (loss) on investments	7,553	(19,589)
Comprehensive loss	<u>\$(8,309,350)</u>	<u>\$(6,055,245)</u>

(5) INVESTMENTS

The following is a summary of available-for-sale investments:

	September 30, 2006	September 30, 2005
Cost	\$ 2,385,570	\$ 2,385,570
Unrealized loss on investments	(47,183)	(54,736)
Fair value	<u>\$ 2,338,387</u>	<u>\$ 2,330,834</u>

(6) COMMITMENTS AND CONTINGENCIES*Contingencies*

The Company is the respondent in an arbitration proceeding before the American Arbitration Association initiated by Competitive Technologies, Inc. (CTI) alleging breach of the terms of a license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction and other actions asserted to arise out of the license agreement. On September 25, 2006 the Company filed a reply to CTI's statement of claim, denying all material allegations asserted by CTI, and asserting counterclaims against CTI for declaratory judgment that claims are barred by the previous settlement agreement with CTI and that bremelanotide is not subject to the license agreement with CTI. Palatin and CTI have not yet completed selection of the arbitration panel, and discovery has not yet been initiated in the arbitration. The Company cannot reasonably predict the outcome of the dispute or reasonably estimate the range of potential loss, if any. However, the Company does not believe that the resolution of this matter will have a material adverse effect on its financial position, results of operations or liquidity.

(7) SUBSEQUENT EVENT

In October 2006, the Company made grants of restricted stock units to three executives for an aggregate of 975,000 shares of common stock. Of the total shares, 325,000 will vest if the quoted market price of Palatin's common stock is \$4.00 or more for twenty consecutive trading days, an additional 325,000 will vest if the quoted market price of Palatin's common stock is \$6.00 or more for twenty consecutive trading days and the remaining 325,000 will vest if the quoted market price of Palatin's common stock is \$8.00 or more for twenty consecutive trading days. The restricted stock units expire four years from the date of grant and require that each grantee retain at least 33% of any vested stock for the

duration of the executive's employment with the Company.

Table of Contents

Item 2. 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 consolidated financial statements filed as part of this report.

Statements in this quarterly report on Form 10-Q, as well as oral statements that may be made by us or by our officers, directors, or employees acting on our behalf, that are not historical facts constitute forward-looking statements, which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the Exchange Act). The forward-looking statements in this quarterly report on Form 10-Q do not constitute guarantees of future performance. Investors are cautioned that statements that are not strictly historical statements contained in this quarterly report on Form 10-Q including, without limitation, current or future financial performance, management's plans and objectives for future operations, clinical trials and results, product plans and performance, management's assessment of market factors, as well as statements regarding our strategy and plans and our strategic partners, constitute forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. Our future operating results are subject to risks and uncertainties and are dependent upon many factors, including, without limitation, the risks identified in this report, in our annual report on Form 10-K for the year ended June 30, 2006 and in our other Securities and Exchange Commission (SEC) filings.

We expect to incur losses in the future as a result of spending on our planned development programs and losses may fluctuate significantly from quarter to quarter.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in the notes to our consolidated financial statements included in this report and in our annual report on Form 10-K for the year ended June 30, 2006. We believe that our accounting policies and estimates relating to revenue recognition, accrued expenses and stock-based compensation are the most critical.

Revenue Recognition

Revenue from corporate collaborations and licensing agreements consists of up-front fees, research and development funding, and milestone payments. Non-refundable up-front fees are deferred and amortized to revenue over the related performance period. Due to the uncertainty inherent in our development programs, including the possibility that a program is terminated prior to completion, we recognize such revenue on a straight-line basis, as we believe that no other basis is more reflective of the pattern over which such revenue is earned. We consider our performance period under the King collaboration to be the period in which we perform development activities during the initial research term, which is currently estimated to be five years from the inception of the agreement. Specific performance periods are not stated in the agreement and are estimated by management based on detailed development programs agreed upon by the parties. Management monitors the progress and results of these development activities and adjusts its estimated performance period accordingly. The actual performance period may vary based on the results of the related development activities, changes in development plans agreed to by the parties, regulatory requirements and other factors. Increases in the estimated performance period would result in increases in the period over which such deferred revenue is to be recognized and corresponding decreases in the amount of revenue recognized each period. As of September 30, 2006, a one-year increase in the estimated period of performance would result in a decrease in the amount of deferred revenue recognized per quarter of approximately \$0.2 million.

Accrued Expenses

A significant portion of our development activities are performed by third parties. We review the activities performed under significant contracts each quarter and accrue expenses and the amount of any reimbursement to be received from our collaborators based upon the estimated amount of work completed. Estimating the value or stage of completion of certain services requires judgment based on available information. If we do not identify services performed for us but not billed by the service-provider, or if we underestimate or overestimate the value of services performed as of a given date, reported expenses will be understated or overstated.

Stock-Based Compensation

The fair value of stock options granted has been calculated using the Black-Scholes model, which requires us to make estimates of volatility and expected option lives. We estimate these factors at the time of grant based on our own prior experience, public sources of information and information for comparable companies. The amount of recorded compensation related to an option grant is not adjusted for subsequent changes in these estimates or for actual experience. The amount of our recorded compensation is also dependent on our estimates of future option

forfeitures and the probability of achievement of performance conditions. If we initially over-estimate future

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Table of Contents

forfeitures, our reported expenses will be understated. Changes in estimated forfeitures will affect our reported expenses in future periods.

Certain options are subject to periodic re-measurement over the vesting period as services are rendered, based on changes in the fair value of our common stock. In addition, the vesting of certain options is dependent on future events. As a result, stock-based compensation charges may vary significantly from period to period. In October 2006, the Company granted restricted stock units to certain executives that vest upon the achievement of specified stock prices. The Company will record expenses in future periods pertaining to these grants, the timing and amount of which may vary based upon the Company's future stock price.

Overview

We are a biopharmaceutical company focused on discovering and developing targeted, receptor-specific small molecule and peptide therapeutics. Our proprietary drug development pipeline is based primarily on melanocortin (MC)-based therapeutics, and we believe we are a leader in this fast growing area of pharmaceutical research and development. Therapeutics affecting the activity of the MC family of receptors may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, cachexia (extreme wasting, generally secondary to a chronic disease), skin pigmentation and inflammation.

In August 2004, we entered into a collaborative development and marketing agreement with King Pharmaceuticals, Inc. (King), a specialty pharmaceutical company, to jointly develop and commercializebremelanotide (formerly known as PT-141), our nasally administered MC-based peptide presently in Phase 2 clinical development for two distinct indications, treatment of male erectile dysfunction (ED) and treatment of female sexual dysfunction (FSD). Pursuant to the terms of the agreement, Palatin and King share all collaboration development costs, marketing costs and net profits derived from net sales ofbremelanotide in North America based on an agreed percentage. Palatin and King currently plan to seek a commercialization partner forbremelanotide for territories outside of North America. We have the option to create, with King, a urology specialty sales force to co-promote the product in the United States if the product is successfully developed and commercialized.

We are in the process of identifying clinical candidate MC therapeutic small molecules for treatment of obesity and related disorders, with programs for both oral and non-oral drug delivery. We are also in the process of identifying natriuretic peptide receptor clinical candidate compounds for the treatment of chronic congestive heart failure (CHF) and acutely decompensated CHF.

In December 2005, we voluntarily suspended the sales, marketing and distribution of NeutroSpec®, our proprietary radiolabeled monoclonal antibody product for imaging and diagnosing equivocal appendicitis, and recalled all existing customer inventories. NeutroSpec, which was approved for marketing by the United States Food and Drug Administration (the FDA) in July 2004, was marketed and distributed by our strategic collaboration partner, Tyco Healthcare Mallinckrodt (Mallinckrodt).

Key elements of our business strategy include: entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates we are investigating; expanding our pipeline through the utilization of our MC expertise and patented drug discovery platform; acquiring synergistic products and technologies; and partially funding our development and discovery programs with the cash flow from our NeutroSpec andbremelanotide collaboration agreements.

We incorporated in Delaware in 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices and research and development facility are located at 4C Cedar Brook Drive, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. We maintain an Internet site at <http://www.palatin.com>, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this quarterly report on Form 10-Q.

Results of Operations

Three Months Ended September 30, 2006 Compared to the Three Months Ended September 30, 2005.

Royalty Revenues For the three months ended September 30, 2006 and 2005, we recognized royalty revenues of \$0 and \$0.9 million, respectively. Royalty revenues in the 2005 period represent amounts earned from Mallinckrodt pursuant to our collaboration agreement, based on a contractual percentage of Mallinckrodt's net sales of NeutroSpec to customers in the period. Sales and marketing activities related to NeutroSpec were suspended in

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Table of Contents

December 2005. We will not earn future royalty revenues related to NeutroSpec unless and until NeutroSpec sales resume.

Licenses, Grants and Contracts For the three months ended September 30, 2006 and 2005, we recognized \$4.9 million and \$4.2 million, respectively, in licenses, grants and contracts revenue consisting of (i) \$4.8 million and \$4.1 million, respectively, related to bremlanotide pursuant to our collaboration agreement with King, and (ii) \$0.1 million and \$0.1 million related to NeutroSpec pursuant to our collaboration agreement with Mallinckrodt. The increase in revenue from King primarily reflects an increase from \$3.3 million in the 2005 period to \$4.0 million in the 2006 period in cost reimbursements from King, which relate to our increased bremlanotide costs, primarily for the conduct of phase 2 clinical trials and process development activities. In the three-month periods ended September 30 of both 2006 and 2005, we also recognized \$0.8 million of deferred revenue from King's 2004 up-front license payment. License and contract revenue from Mallinckrodt in the three months ended September 30, 2006 reflects Mallinckrodt's share of the costs incurred in certain NeutroSpec development activities. We expect to continue to earn contract revenue from King as the development of bremlanotide continues, in the form of reimbursement of shared development costs and the recognition of deferred license fees. The amount of such revenue will depend on a number of factors, including bremlanotide development activities performed and decisions about the division of responsibility for such activities between us and King. Future cost reimbursements from Mallinckrodt are dependent upon decisions we make together with Mallinckrodt concerning future NeutroSpec development activities. We may also earn contract revenue from Mallinckrodt, subject to decisions concerning future NeutroSpec activities, and King based on the attainment of certain development milestones.

Royalty Expense For the three months ended September 30, 2006 and 2005, royalty expense amounted to \$0 and \$0.2 million, respectively. Royalties represented amounts due licensors based primarily on Mallinckrodt's net sales of NeutroSpec to customers. Sales and marketing activities related to NeutroSpec were suspended in December 2005. We will not incur future royalty expenses related to NeutroSpec unless and until commercial sales of NeutroSpec resume.

Research and Development Research and development expenses increased to \$12.1 million for the three months ended September 30, 2006 from \$9.4 million for the three months ended September 30, 2005.

Research and development expenses related to bremlanotide increased to \$7.8 million in the 2006 period from \$5.1 million in the 2005 period, primarily due to increased costs of ongoing clinical trials, including our share of increased clinical development activities performed by King, and higher process development costs. In the three months ended September 30, 2006, we and King completed two Phase 2B studies evaluating the safety and efficacy of bremlanotide in patients suffering from mild to severe ED, with one trial limited to non-diabetic patients and the other to diabetic patients, and initiated patient enrollment in a Phase 2B at home clinical trial in female patients with FSD. Associated costs include fees to clinicians, costs of drug supplies and study monitoring and management. We expect to spend approximately \$10 million to \$15 million of direct costs (excluding allocated general expenses) on bremlanotide in the remainder of the current fiscal year to conduct clinical studies for ED and FSD and continue related process and development activities prior to initiating Phase 3 clinical trials. A majority of the additional direct costs will be reimbursed by our collaboration partner, King.

Research and development expenses related to our MIDAS program increased from \$0.4 million for the three months ended September 30, 2005 to \$0.8 million for the three months ended September 30, 2006, primarily as a result of additional contract services for assistance with the optimization of lead compounds. We expect to spend approximately \$2 million to \$4 million of additional direct costs during the remainder of the current fiscal year to continue laboratory research on various compounds in preparation for filing an Investigational New Drug Application and commencing clinical trials. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the success of our discovery programs, preclinical studies, our ability to progress a compound into human clinical trials and discussions with potential development partners.

Research and development spending on NeutroSpec decreased from \$0.6 million for the three months ended September 30, 2005 to less than \$0.1 million for the three months ended September 30, 2006 as a result of lower costs related to manufacturing and process development activities. We have suspended ongoing clinical trials and plans for future trials, including studies to evaluate NeutroSpec's market potential as an imaging agent for other indications such as osteomyelitis (infection deep inside a bone), fever of unknown origin, post surgical infection, inflammatory bowel disease and pulmonary imaging. We expect to spend approximately \$0.1 million to \$0.5 million of direct costs on NeutroSpec during the remainder of the current fiscal year to conduct selected studies, review the safety of NeutroSpec and explore other indications. A significant portion of these costs will be reimbursed by our collaboration partner, Mallinckrodt. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the review of NeutroSpec safety and discussions with both the FDA and Mallinckrodt.

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Table of Contents

The historical amounts of project spending above exclude general research and development spending, which increased from \$3.3 million for the three months ended September 30, 2005 to \$3.6 million for the three months ended September 30, 2006, primarily due to increased personnel costs and the expansion of facilities.

Cumulative spending from inception to September 30, 2006 on our bremelanotide, NeutroSpec and MIDAS programs amounts to approximately \$95.8 million, \$54.7 million and \$23.5 million, respectively. Due to risk factors described in our periodic filings with the SEC, including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and large-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, significant related net cash inflows will be generated.

General and Administrative General and administrative expenses in the three months ended September 30, 2006 and 2005 amounted to \$1.6 million and \$1.8 million, respectively. The decrease in expenses for the 2006 period primarily reflects lower insurance expense and decreases in miscellaneous taxes and other overhead expenses, which were partially offset by increased consulting costs related to the bremelanotide program.

Liquidity and Capital Resources

Since inception, we have incurred net operating losses, primarily related to spending on our research and development programs. We have financed our net operating losses primarily through equity financings and revenue received under collaborative agreements.

Our product candidates are at various stages of research and development and some may never be successfully developed or commercialized. We will need regulatory approval to market and sell bremelanotide and obesity and CHF products. In addition, in December 2005, we voluntarily suspended the sales, marketing and distribution of NeutroSpec and recalled all existing customer inventories. Our product candidates under development will require significant further research, development and testing. We may experience uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, which may include unanticipated problems and additional costs relating to:

- the development and testing of products in animals and humans;
- product approval or clearance;
- regulatory compliance;
- good manufacturing practices;
- intellectual property rights;
- product introduction; and
- marketing, sales and competition.

Failure to obtain timely regulatory approval for our other product candidates and indications would impact our ability to increase revenues and could make it more difficult to attract investment capital for funding our operations. Any of these possibilities could materially and adversely affect our operations.

During the three months ended September 30, 2006, we used \$10.0 million of cash for our operating activities, compared to \$2.4 million in the three months ended September 30, 2005. Lower net cash outflows from operations in the 2005 quarter resulted primarily from lower operating expenses and the timing of the receipt of reimbursements from King for bremelanotide costs. In the three months ended September 30, 2005, our accounts receivable balance decreased \$4.3 million. Our periodic accounts receivable balances will continue to be highly dependent on the timing of such receipts and the division of development responsibilities between us and King.

During the three months ended September 30, 2006, there were no proceeds from financing activities. In the three months ended September 30, 2005, net proceeds from the issuance of common stock and warrants amounted to \$10.0 million, reflecting proceeds from the sale of common stock and warrants to King, related to our collaboration agreement.

We have incurred cumulative 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 expect that our cash, cash equivalents and available-for-sale investments as of September 30, 2006, together with expected revenue from collaboration and license agreements and other income will be adequate to fund the Company's operations for at least the next twelve months. No assurance can be given that we will earn future milestone payments that are contingent on specified events or that we will not consume a significant amount of our available resources before

that time. We plan to continue to monitor the progress of our development programs and the timing and amount of related expenditures and potential milestone receipts, refine our operations, control expenses, evaluate alternative methods to conduct our business and seek additional financing and sharing of development costs through strategic collaboration agreements or other resources.

Table of Contents

We are actively searching for certain products and technologies to license or acquire, now or in the future, and expect to continue to do so. 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 or whether we will be able to obtain additional funding if such an acquisition is located.

Our license agreements related to NeutroSpec require royalty payments by us based on commercial net sales and payments of up to \$2.25 million contingent on the achievement of specified cumulative net margins on sales by Mallinckrodt. No contingent amounts will be payable related to NeutroSpec unless we recommence sales and marketing of NeutroSpec. We do not reasonably expect to make any such contingent payments during the next twelve months. We also have a license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction. The license agreement requires contingent payments based on certain upfront fees we receive as a result of a sublicense. We do not reasonably expect to sublicense such rights or make any material contingent payments during the next twelve months.

We anticipate incurring additional losses over at least the next few years. 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk. Our exposure to market risk from changes in interest rates relates primarily to our investment portfolio. As of September 30, 2006, our cash and cash equivalents were \$18.2 million and investments, which consisted of mutual funds, were \$2.3 million. Due to the average maturity of our investment portfolio, we do not believe that short term fluctuations in interest rates would materially affect the value of our securities.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective. There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

As discussed in our annual report on Form 10-K for our fiscal year ended June 30, 2006, we are the respondent in an arbitration proceeding before the American Arbitration Association initiated by Competitive Technologies, Inc. (CTI) alleging breach of the terms of our license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction and other actions asserted to arise out of the license agreement. On September 25, 2006, we filed a reply to CTI 's statement of claim, denying all material allegations asserted by CTI, and asserting counterclaims against CTI for declaratory judgment that claims are barred by the previous settlement agreement with CTI and that bremelanotide is not subject to the license agreement with CTI. We and CTI have not yet completed selection of the arbitration panel, and discovery has not yet been initiated in the arbitration.

Item 1A. Risk Factors.

There has been no material change in our risk factors as previously disclosed in our annual report on Form 10-K for the fiscal year ended June 30, 2006 in response to Item 1A., Part 1 of such Form 10-K.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

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

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibits filed with this report:

- 31.1 Certification of Chief Executive Officer.
- 31.2 Certification of Chief Financial Officer.
- 32.1 Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as added by Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as added by Section 906 of the Sarbanes-Oxley Act of 2002.

Signatures

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Palatin Technologies, Inc.
(Registrant)

Date: November 9, 2006

/s/ Carl Spana
Carl Spana, Ph.D.
President and
Chief Executive Officer

Date: November 9, 2006

/s/ Stephen T. Wills
Stephen T. Wills
Executive Vice President and
Chief Financial Officer (Principal
Financial and Accounting Officer)

EXHIBIT INDEX

- 31.1 Certification of Chief Executive Officer.
- 31.2 Certification of Chief Financial Officer.
- 32.1 Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as added by Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as added by Section 906 of the Sarbanes-Oxley Act of 2002.