PALATIN TECHNOLOGIES INC

Form 10-Q

November 14, 2008

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## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

	FORM	I 10-Q
(Mark One)		
[X]	QUARTERLY REPORT PURSUANT TO SECTION 13 For the quarterly period e	OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 nded September 30, 2008
	O	r
[]	TRANSITION REPORT PURSUANT TO SECTION 13  For the transition period from	OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 to
	Commission file n	number 001-15543
	PALATIN TECH	NOLOGIES, INC.
	(Exact name of registrant	as specified in its charter)
	Delaware	95-4078884
	(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	4C Cedar Brook Drive	
	Cranbury, New Jersey	08512
	(Address of principal executive offices)	(Zip Code) 95-2200
	* /	umber, including area code)
		uired to be filed by Section 13 or 15(d) of the Securities Exchange Act he registrant was required to file such reports), and (2) has been subject
to such filing	requirements for the past 90 days. Yes X No O	
	e the definitions of large accelerated filer, accelerated f	an accelerated filer, a non-accelerated filer, or a smaller reporting iler and smaller reporting company in Rule 12b-2 of the Exchange Act.
	Large accelerated filer O	Accelerated filer O
	Non-accelerated filer O	Smaller reporting company X
	(Do not check if a smaller reporting company)	
Indicate by c	heck mark whether the registrant is a shell company (as defi	ined in Rule 12b-2 of the Exchange Act). Yes o No x
As of Novem	aber 13, 2008, 86,662,901 shares of the registrant s commo	n stock, par value \$.01 per share, were outstanding.

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#### PART I FINANCIAL INFORMATION

#### **Item 1. Financial Statements**

#### PALATIN TECHNOLOGIES, INC. Consolidated Balance Sheets (unaudited)

	Se	ptember 30, 2008	June 30, 2008
ASSETS			
Current assets:			
Cash and cash equivalents	\$	4,735,975	\$ 9,421,770
Available-for-sale investments		3,352,712	3,352,771
Accounts receivable		342,925	5,747
Prepaid expenses and other current assets		403,719	484,362
Total current assets		8,835,331	13,264,650
Property and equipment, net		4,796,173	5,128,076
Restricted cash		475,000	475,000
Other assets		261,219	257,198
Total assets	\$	14,367,723	\$ 19,124,924
LIABILITIES AND STOCKHOLDERS EQUITY Current liabilities:			
Capital lease obligations, current portion	\$	237,280	\$ 263,128
Accounts payable		580,844	635,183
Accrued expenses		1,643,576	1,666,628
Accrued compensation		447,247	767,509
Deferred revenue, current portion		1,666,669	1,666,669
Total current liabilities		4,575,616	4,999,117
Capital lease obligations, net of current portion		80,734	121,629
Deferred rent, net of current portion		1,371,608	1,479,794
Deferred revenue, net of current portion		5,555,552	5,972,220
Total liabilities		11,583,510	12,572,760
Total habilities		11,365,310	12,372,700
Commitments and contingencies (Note 6)			
Stockholders equity:			
Preferred stock of \$.01 par value - authorized 10,000,000 shares;			
Series A Convertible; issued and outstanding 4,997 shares as of			
September 30, 2008 and June 30, 2008, respectively		50	50
Common stock of \$.01 par value authorized 150,000,000 shares;			
issued and outstanding 85,546,077 and 85,524,077 shares as of			
September 30, 2008 and June 30, 2008, respectively		855,461	855,241
Additional paid-in capital		208,761,597	208,247,194

Accumulated other comprehensive income	29,058	29,117
Accumulated deficit	(206,861,953)	(202,579,438)
Total stockholders equity	2,784,213	6,552,164
Total liabilities and stockholders equity	\$ 14,367,723	\$ 19,124,924

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

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

	Three Months Ended September 30,		
	2008	2007	
REVENUES:			
Licenses and contracts	\$ 753,846	\$ 8,977,731	
OPERATING EXPENSES:			
Research and development	3,657,999	7,943,877	
General and administrative	1,456,848	1,659,010	
Total operating expenses	5,114,847	9,602,887	
Loss from operations	(4,361,001)	(625,156)	
OTHER INCOME (EXPENSE):			
Investment income	82,980	396,621	
Interest expense	(4,494)	(18,229)	
Total other income, net	78,486	378,392	
NET LOSS	\$ (4,282,515)	\$ (246,764)	
Basic and diluted net loss per common share	\$ (0.05)	\$ (0.00)	
Weighted average number of common shares outstanding used in computing basic and			
diluted net loss per common share	85,524,316	85,177,298	

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

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

	Three Months Ended September 30,		
	2008	2007	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (4,282,515)	\$ (246,764)	
Adjustments to reconcile net loss to net cash			
used in operating activities:			
Depreciation and amortization	335,743	340,724	
Stock-based compensation	514,623	450,463	
Changes in operating assets and liabilities:			
Accounts receivable	(337,178)	147,572	
Prepaid expenses and other assets	76,622	1,038,067	
Accounts payable	(54,339)	(154,548)	
Accrued expenses and other liabilities	(451,500)	(412,871)	
Deferred revenues	(416,668)	(8,169,031)	
Net cash used in operating activities	(4,615,212)	(7,006,388)	
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(3,840)	(156,321)	
Net cash used in investing activities	(3,840)	(156,321)	
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments on capital lease obligations	(66,743)	(89,634)	
Proceeds from exercise of common stock warrants		110,229	
Net cash provided by (used in) financing activities	(66,743)	20,595	
NET DECREASE IN CASH AND			
CASH EQUIVALENTS	(4,685,795)	(7,142,114)	
CASH AND CASH EQUIVALENTS, beginning			
of period	9,421,770	31,447,615	
CASH AND CASH EQUIVALENTS, end of period	\$ 4,735,975	\$ 24,305,501	
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash paid for interest	\$ 10,494	\$ 18,229	
Equipment acquired under financing agreements	-	\$ 186,989	
Unrealized gain (loss) on available-for-sale investments	\$ (59)	\$ 15,814	

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

#### 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 dedicated to the development of peptide, peptide mimetic and small molecule agonist compounds with a focus on melanocortin and natriuretic peptide receptor systems. Palatin has a diverse pipeline of active development programs targeting melanocortin and natriuretic receptors, including proposed products in the cardiovascular field for treatment of heart failure, hard-to-control hypertension and for cardiac surgery organ protection, and proposed products for sexual dysfunction, obesity and metabolic syndrome. The melanocortin system is involved in a large and diverse number of physiologic functions, and therapeutic agents modulating this system may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, ischemia reperfusion injury, hemorrhagic shock and inflammation-related diseases. The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of heart failure, hypertension and other cardiovascular diseases.

The Company s products in development include PL-3994, a peptidomimetic natriuretic peptide receptor A agonist, for treatment of heart failure and difficult-to-control hypertension, bremelanotide, a peptide melanocortin receptor agonist, for prevention of organ damage secondary to cardiac surgery and related indications, and PL-6983, a peptide melanocortin receptor agonists, for treatment of female sexual dysfunction. The Company has a licensing and research collaboration agreement with AstraZeneca AB (AstraZeneca) to discover, develop and commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome. Sales, marketing and distribution of the Company s NeutroSpec product, a radiolabeled monoclonal antibody product for imaging and diagnosing infection which is the subject of a strategic collaboration agreement with the Mallinckrodt division of Covidien Ltd. (Mallinckrodt), were voluntarily suspended in December 2005 following the occurrence of certain serious adverse events involving patients who received NeutroSpec. Significant development activities pertaining to NeutroSpec are currently suspended while the Company and Mallinckrodt evaluate future development and marketing alternatives.

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, partial funding of the Company s development and discovery programs with the cash flow from collaboration agreements and, depending on the availability of sufficient funding, expansion of the Company s pipeline through the utilization of its melanocortin expertise and drug discovery technologies and opportunistic acquisition of synergistic products and technologies.

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, 2008 and incurred a net loss for the three months ended September 30, 2008. 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 preclinical 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.

As of September 30, 2008, the Company s cash and cash equivalents were \$4,735,975 and its available-for-sale investments were \$3,352,712. The accompanying consolidated financial statements have been prepared assuming that the Company continues as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company is exploring sources of additional capital through public or private financing or collaborative agreements with the intent to raise additional capital. There is no assurance that required additional capital will be obtained on terms acceptable to the Company or at all. These matters raise substantial doubt over the Company s ability to continue as a going concern.

The nature and timing of the Company s development activities are highly dependent on its financing activities. Management plans to continue to refine its operations, control expenses, evaluate alternative methods to conduct its business, and seek available sources of public or private financing and sharing of development costs through collaborative agreements or other arrangements. Should appropriate sources of financing not be available,

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management will curtail operations and delay clinical trials and research activities until such time, if ever, as appropriate financing is available. There can be no assurance that the Company will be able to obtain financing when required or that financing efforts will be successful.

Concentrations Concentrations in the Company s assets and operations subject it to certain related risks. Financial instruments that 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 accounts receivable balance as of September 30, 2008 consists of amounts due from its collaboration partners, including \$337,178 due from AstraZeneca and \$5,747 due from Mallinckrodt. Revenues from collaboration partners as a percentage of total revenues were as follows:

	Three Months Ended September 30,		
	2008	2007	
AstraZeneca	100%	91%	
King Pharmaceuticals, Inc.	-	8%	
Mallinckrodt	-	1%	

#### (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, 2008, and its results of operations and its cash flows for the three months ended September 30, 2008 and 2007. The results of operations for the three-month period ended September 30, 2008 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, 2009.

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 year ended June 30, 2008, filed with the Securities and Exchange Commission (SEC), which includes consolidated financial statements as of June 30, 2008 and 2007 and for each of the fiscal years in the three-year period ended June 30, 2008.

#### (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 Cash Equivalents 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 based on quoted market prices. Unrealized holding gains and losses, net of the related tax effect, if any, are generally excluded from earnings and are reported in accumulated other comprehensive income/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

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obligations. Management believes that the carrying value of these assets and liabilities are representative of their respective fair values based on quoted market prices for investments and the short-term nature of the other instruments.

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 expense. Maintenance and repairs are expensed as incurred while expenditures that extend the useful life of an asset are capitalized.

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 cash flows from the asset 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 cash flows based on reasonable and supportable assumptions.

*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, as well as tenant allowances for leasehold improvements. Rent expenses are being recognized ratably over the terms of the leases.

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. The Company estimates the performance period as the period in which it performs certain development activities under the applicable agreement. Reimbursements for research and development activities 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, provided that such milestone is substantive in nature.

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 Effective July 1, 2005, the Company adopted Statement of Financial Accounting Standards (SFAS) 123(R), Share-Based Payment, using the modified prospective method. 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 financial statements, based on 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 (EITF) Issue 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, and SFAS 123(R).

The Company determines the value of stock options utilizing the Black-Scholes option pricing model. Compensation costs for share-based awards with pro rata vesting are allocated to periods on a 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 basis 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 or operating loss and tax credit carryforwards are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized 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 consideration of tax laws that may limit the Company s ability to utilize its net operating loss carryforwards.

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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, including stock options and warrants, restricted stock units and shares of Series A Convertible Preferred Stock. As of September 30, 2008 and 2007, common shares issuable upon conversion of Series A Convertible Preferred Stock, the vesting of restricted stock units and the exercise of outstanding options and warrants amounted to an aggregate of 15,754,226 and 16,266,314 shares, respectively, and were not included in the computation of Diluted EPS because to do so would have been anti-dilutive for the periods presented.

Recently Issued Accounting Pronouncements In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, Fair Market Measurements. SFAS 157 clarifies the definition of fair value, establishes a framework for measuring fair value and expands disclosure on fair value measurement. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years; however, the FASB did provide a one-year deferral for the implementation of SFAS 157 for certain non-financial assets and liabilities.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs include quoted prices for identical or similar assets and liabilities that are not active, quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on management s own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of September 30, 2008:

#### Fair value measurements at September 30, 2008 using

	carrying value as of ember 30, 2008	act	oted prices in tive markets (Level 1)	ets active markets		Quoted price active mark (Level 3)	
Available-for-sale-investments	\$ 3,352,712	\$	3,352,712	\$	-	\$	-

Available-for-sale-investments are measured at fair value using quoted market prices and are classified within Level 1 of the valuation hierarchy. The adoption of SFAS 157 did not have any impact on the Company s consolidated results of operations and financial position.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS 159 permits entities to measure many financial instruments and certain other items at fair value at specified election dates. Under SFAS 159, any unrealized holding gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date. If elected, the fair value option (1) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (2) is irrevocable (unless a new election date occurs); and (3) is applied only to entire instruments and not to portions of instruments. SFAS 159 is effective as of an entity s first fiscal year that begins after November 15, 2007. The adoption of SFAS 159 did not have a material impact on the Company s consolidated results of operations and financial position.

In June 2007, the FASB issued EITF Issue 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, which applies to companies involved in research and development activities that make non-refundable advance payments for goods that will be used, or for services that will be performed, in future research and development activities. EITF Issue 07-3 is effective for financial statements issued for fiscal years beginning after December 15, 2007. The adoption of EITF Issue 07-3 did not have a material impact on the Company's consolidated results of operations and financial position.

In December 2007, the FASB issued EITF Issue 07-1, Accounting for Collaborative Arrangements, which applies to collaborative arrangements that are conducted by the participants without the creation of a separate legal entity for the arrangements and clarifies, among other things, how to determine whether a collaborative agreement is within the scope of this issue. EITF Issue 07-1 is effective for financial statements issued for fiscal

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years beginning after December 15, 2008. The Company does not expect the adoption of EITF Issue 07-1 to have a material impact on its consolidated results of operations and financial position.

#### (4) COMPREHENSIVE LOSS

Comprehensive loss consists of the following:

	Three Months Ended September 30,			
		2008		2007
Net loss	\$	(4,282,515)	\$	(246,764)
Unrealized gain (loss) on available-for-sale investments		(59)		15,814
Comprehensive loss	\$	(4,282,574)	\$	(230,950)

#### (5) INVESTMENTS

The following is a summary of available-for-sale investments, which consist of mutual funds that invest primarily in debt instruments:

	September 30, 2008		June 30, 2008	
Cost	\$	3,323,654	\$	3,323,654
Unrealized gains		29,058		29,117
Fair Value	\$	3,352,712	\$	3,352,771

#### (6) COMMITMENTS AND CONTINGENCIES

Contingencies The Company accounts for litigation losses in accordance with SFAS 5, Accounting for Contingencies. Under SFAS 5, loss contingency provisions are recorded for probable losses when management is able to reasonably estimate the loss. Any outcome upon settlement that deviates from the Company s best estimate may result in additional expense or in a reduction in expense in a future accounting period. The Company records legal expenses associated with such contingencies as incurred.

The Company is subject to an inherent risk of product liability claims as a result of the testing and marketing of its products. In December 2005, as a result of safety concerns raised in connection with the use of NeutroSpec, the Company and Mallinckrodt suspended NeutroSpec sales and marketing activities. If any claim is asserted based on the use of NeutroSpec, the Company may incur future expenses or losses in connection with the related litigation.

#### (7) STOCKHOLDERS EQUITY

On September 25, 2007, the Company issued grants of restricted stock units under the Company s 2005 Stock Plan totaling in the aggregate 1,573,915 shares of common stock as retention bonuses to its employees, other than the executive officers, that were not affected by the September 2007 reduction in workforce. On September 30, 2008, after adjusting for forfeitures and early vesting due to involuntary position elimination, 1,138,824 shares of common stock vested. The Company amortized the fair value of these restricted stock units, totaling approximately \$676,000, over the vesting period. For the three-month period ended September 30, 2008, the Company recognized approximately \$133,000 of stock-based compensation expense related to these restricted stock units.

Stock-based compensation costs for the three months ended September 30, 2008 for stock options and equity-based instruments issued other than the restricted stock units referenced above totaled approximately \$382,000.

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#### 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 as amended (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, 2008 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.

In this quarterly report on Form 10-Q, references to we, our, us or Palatin means Palatin Technologies, Inc.

#### **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, 2008, and have not changed as of September 30, 2008. We believe that our accounting policies and estimates relating to revenue recognition, accrued expenses and stock-based compensation are the most critical.

#### Overview

We are a biopharmaceutical company dedicated to the development of peptide, peptide mimetic and small molecule compounds with a focus on melanocortin and natriuretic peptide receptor systems. We have a diverse pipeline of active development programs, including development of proposed products in the cardiovascular field for treatment of heart failure, hard-to-control hypertension and for cardiac surgery organ protection, and proposed products for sexual dysfunction, obesity and metabolic syndrome. The melanocortin system is involved in a large and diverse number of physiologic functions, and therapeutic agents modulating this system may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, ischemia reperfusion injury (injury resulting from inadequate blood flow or reintroduction of blood flow), hemorrhagic shock and inflammation-related diseases. The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of heart failure, hypertension and other cardiovascular diseases.

We have the following products in development:

PL-3994, a peptidomimetic natriuretic peptide receptor A (NPRA) agonist, for treatment of heart failure (HF), including chronic HF and acute HF.

 $PL-3994\ for\ treatment\ of\ difficult-to-control\ hypertension,\ including\ dialysis\ patients\ with\ hypertension.$ 

Bremelanotide, a peptide melanocortin receptor agonist, for prevention of organ damage secondary to cardiac surgery and related indications.

PL-6983, a peptide melanocortin receptor agonist, for treatment of female sexual dysfunction (FSD).

Melanocortin receptor-based compounds for treatment of obesity and related metabolic syndrome pursuant to an ongoing research collaboration and global license with AstraZeneca AB.

NeutroSpec®, a radiolabeled monoclonal antibody product for imaging and diagnosing infection, which is the subject of a strategic collaboration agreement with the Mallinckrodt division of Covidien Ltd. (Mallinckrodt). We have suspended ongoing clinical trials and regulatory approvals of NeutroSpec while we and Mallinckrodt evaluate future development and marketing activities involving NeutroSpec.

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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 developing; partially funding our development and discovery programs with the cash flow from our collaboration agreements; and, depending on the availability of sufficient funding, expanding our pipeline by using our expertise in drug discovery technologies for melanocortin and natriuretic peptide receptor systems and acquiring synergistic products and technologies.

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 in it or connected to it shall not be deemed to be incorporated into this quarterly report on Form 10-Q.

#### **Results of Operations**

Three Months Ended September 30, 2008 Compared to the Three Months Ended September 30, 2007

Licenses and Contracts For the three months ended September 30, 2008, we recognized \$0.8 million in licenses and contract revenue related to our license agreement with AstraZeneca. For the three months ended September 30, 2007, we recognized \$9.0 million in licenses and contracts revenue, consisting of (i) \$8.2 million, related to bremelanotide for erectile dysfunction (ED) and FSD indications pursuant to our collaboration agreement with King Pharmaceuticals, Inc. (King), (ii) \$0.7 million related to our license agreement with AstraZeneca, and (iii) \$0.1 million related to NeutroSpec pursuant to our collaboration agreement with Mallinckrodt.

There was no revenue related to King in 2008 as a result of the termination of our collaboration agreement with King and the recognition in September 2007 of the remaining deferred license revenue pursuant to King s up-front payment. License and contract revenue from AstraZeneca for the three months ended September 30, 2008 consists of \$0.3 million of revenue related to our research services performed during said period and \$0.4 million of license revenue related to AstraZeneca s up-front license fee. Contract revenue from Mallinckrodt reflects Mallinckrodt s share of the costs incurred in certain NeutroSpec development activities. Future contract revenue from AstraZeneca and Mallinckrodt, in the form of reimbursement of shared development costs or the recognition of deferred license fees, will fluctuate based on development activities in our obesity and NeutroSpec programs. We may also earn contract revenue based on the attainment of certain development milestones.

Research and Development Research and development expenses decreased to \$3.7 million for the three months ended September 30, 2008 from \$7.9 million for the three months ended September 30, 2007.

Research and development expenses related to bremelanotide for ED and FSD were \$0 for the three months ended September 30, 2008 compared to \$2.5 million for the same period in 2007. The amount for the three months ended September 30, 2007 included both third-party costs incurred by us and partially reimbursed by King and our share of costs for development activities performed by King. Research and development expenses related to bremelanotide for ED and FSD changed as a result of (i) the completion of certain Phase 2B trials on both men and women, and (ii) the decision to not initiate Phase 3 clinical trials for ED, and (iii) the strategic restructuring and refocusing of our clinical-stage product portfolio development programs. Similar to the recognition of license revenue explained above, the three months ended September 30, 2007 includes the recognition of \$0.8 million of deferred costs based on the termination of our collaboration agreement with King.

Research and development expenses related to our PL-3994, bremelanotide for prevention of organ damage, PL-6983, obesity, NeutroSpec and other preclinical programs were \$1.1 million for the three months ended September 30, 2008 compared to \$1.0 million for the three months ended September 30, 2007. Spending to date has been primarily related to the identification and optimization of lead compounds, and secondarily to preclinical studies and a Phase 1 and a Phase 2a trial with PL-3994. The amount of such spending and the nature of future development activities are dependant on a number of factors, including primarily the availability of funds to support future development activities, success of our clinical trials, preclinical and discovery programs, and our ability to progress compounds in addition to PL-3994 into human clinical trials.

The historical amounts of project spending above exclude general research and development spending, which decreased to \$2.6 million for the three months ended September 30, 2008 compared to \$4.4 million for the

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three months ended September 30, 2007. The decrease is primarily related to the reductions in workforce initiated in September 2007 and May 2008

Cumulative spending from inception to September 30, 2008 on our bremelanotide, NeutroSpec and other programs (which includes PL-3994, PL-6983, obesity, and other discovery programs) amounts to approximately \$121.6 million, \$55.4 million and \$46.6 million, respectively. Due to various 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, related net cash inflows will be generated.

*General and Administrative* General and administrative expenses decreased to \$1.5 million for the three months ended September 30, 2008 compared to \$1.7 million for the three months ended September 30, 2007. The decrease is primarily related to the reductions in workforce initiated in September 2007 and May 2008.

#### **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 amounts received under collaborative agreements.

Our product candidates are at various stages of development and will require significant further research, development and testing and some may never be successfully developed or commercialized. 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;
marketing, sales and competition; and
obtaining sufficient capital.

Failure to obtain timely regulatory approval for our product candidates and indications would impact our ability to generate 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 and require us to curtail or cease certain programs.

During the three months ended September 30, 2008, we used \$4.6 million of cash for our operating activities, compared to \$7.0 million used in the three months ended September 30, 2007. Lower net cash outflows from operations in the three months ended September 30, 2008 resulted primarily from lower operating expenses. Our periodic accounts receivable balances will continue to be highly dependent on the timing of receipts from collaboration partners and the division of development responsibilities between us and our collaboration partners.

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. As of September 30, 2008, our cash and cash equivalents were \$4.7 million and our available-for-sale investments were \$3.4 million. This raises substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that we continue as a going concern.

We intend to seek additional capital through public or private equity financings, collaborative arrangements on our product candidates, milestone payments or other sources. However, additional funding may not be available on acceptable terms or at all. We anticipate receiving payments totaling \$5 million from AstraZeneca by the end of the first quarter of calendar year 2009, provided we achieve specified objectives by that time. No assurance can be given that we will achieve the specified objectives by that time or at all. We are also negotiating an extension of the collaboration portion of our agreement with AstraZeneca, which if successfully concluded would result in support for an increased number of Palatin employees. If adequate funds are not available, we will further curtail operations significantly, including the delay, modification or cancelation of product candidate development plans and further decreases in staffing levels. We may also be required to seek collaborators for our product

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candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available, and relinquish, license or otherwise dispose of rights on unfavorable terms to technologies and product candidates that we would otherwise seek to develop or commercialize ourselves.

The nature and timing of our development activities are highly dependent on our financing activities. 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.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies or sell or license our product candidates to others. If we are successful in identifying a product or technology for an 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 we identify such an acquisition.

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 preclinical 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 cash, cash equivalents and available-for-sale investments (collectively referred to as our investment portfolio). As of September 30, 2008, our cash and cash equivalents were \$4.7 million and investments, which consisted of mutual funds, were \$3.4 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 it.

#### Item 4T. 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.

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#### PART II OTHER INFORMATION

#### Item 1. Legal Proceedings.

We may be involved, from time to time, in various claims and legal proceedings arising in the ordinary course of our business. We are not currently a party to any such claims or proceedings that, if decided adversely to us, would either individually or in the aggregate have a material adverse effect on our business, financial condition or results of operations.

#### Item 1A. Risk Factors.

There have been no material changes to our risk factors disclosed in Part I, Item 1A. of our annual report on Form 10-K for the fiscal year ended June 30, 2008.

#### 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 or furnished 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 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. \*

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

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#### **SIGNATURES**

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

Palatin Technologies, Inc.

(Registrant)

Date: November 14, 2008 /s/ Carl Spana

Carl Spana, Ph.D. President and

Chief Executive Officer (Principal

**Executive Officer**)

Date: November 14, 2008 /s/ Stephen T. Wills

Stephen T. Wills

Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

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