

PALATIN TECHNOLOGIES INC  
Form 10-Q  
November 13, 2009

---

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, 2009

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) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

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 12, 2009, 96,172,499 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

---

PALATIN TECHNOLOGIES, INC.  
Table of Contents

	<u>Page</u>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b>Item 1. <u>Financial Statements (Unaudited)</u></b>	
<u>Consolidated Balance Sheets as of September 30, 2009 and June 30, 2009</u>	2
<u>Consolidated Statements of Operations for the Three Months Ended September 30, 2009 and 2008</u>	3
<u>Consolidated Statements of Cash Flows for the Three Months Ended September 30, 2009 and 2008</u>	4
<u>Notes to Consolidated Financial Statements</u>	5
<b>Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	10
<b>Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	13
<b>Item 4. <u>Controls and Procedures</u></b>	13
<b><u>PART II OTHER INFORMATION</u></b>	
<b>Item 1. <u>Legal Proceedings</u></b>	14
<b>Item 1A. <u>Risk Factors</u></b>	14
<b>Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	14
<b>Item 3. <u>Defaults Upon Senior Securities</u></b>	14
<b>Item 4. <u>Submission of Matters to a Vote of Security Holders</u></b>	14
<b>Item 5. <u>Other Information</u></b>	14
<b>Item 6. <u>Exhibits</u></b>	14
<b><u>SIGNATURES</u></b>	

Table of Contents**PART I - FINANCIAL INFORMATION****Item 1. Financial Statements****PALATIN TECHNOLOGIES, INC.  
and Subsidiary****Consolidated Balance Sheets  
(unaudited)**

	<b>September 30, 2009</b>	<b>June 30, 2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,188,173	\$ 4,378,662
Available-for-sale investments	3,466,673	3,439,650
Accounts receivable	3,233,278	508,528
Prepaid expenses and other current assets	364,239	492,824
Total current assets	11,252,363	8,819,664
Property and equipment, net	3,338,705	3,650,783
Restricted cash	475,000	475,000
Other assets	250,022	254,364
Total assets	\$ 15,316,090	\$ 13,199,811
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Capital lease obligations	\$ 45,154	\$ 87,675
Accounts payable	410,984	206,363
Accrued expenses	1,048,974	1,420,741
Deferred revenue	6,311,416	6,955,553
Total current liabilities	7,816,528	8,670,332
Capital lease obligations	29,224	33,954
Deferred rent	1,056,673	1,182,026
Total liabilities	8,902,425	9,886,312
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, 2009 and June 30, 2009, respectively	50	50
Common stock of \$.01 par value - authorized 150,000,000 shares; issued and outstanding 96,155,249 and 86,662,901 shares as of September 30, 2009 and June 30, 2009, respectively	961,552	866,629
Additional paid-in capital	212,727,664	209,712,379
Accumulated other comprehensive income	143,134	116,111

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

Accumulated deficit	(207,418,735)	(207,381,670)
Total stockholders' equity	6,413,665	3,313,499
Total liabilities and stockholders' equity	\$ 15,316,090	\$ 13,199,811

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

Table of Contents

**PALATIN TECHNOLOGIES, INC.  
and Subsidiary**

**Consolidated Statements of Operations**  
(unaudited)

	<b>Three Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
REVENUES	\$ 3,662,619	\$ 753,846
OPERATING EXPENSES:		
Research and development	2,669,564	3,657,999
General and administrative	1,153,731	1,456,848
Total operating expenses	3,823,295	5,114,847
Loss from operations	(160,676)	(4,361,001)
OTHER INCOME (EXPENSE):		
Investment income	33,312	82,980
Interest expense	(4,701)	(4,494)
Gain on sale of supplies	95,000	-
Total other income, net	123,611	78,486
NET LOSS	\$ (37,065)	\$ (4,282,515)
Basic and diluted net loss per common share	\$ (0.00)	\$ (0.05)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	91,306,223	85,524,316

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

Table of Contents

**PALATIN TECHNOLOGIES, INC.  
and Subsidiary**

**Consolidated Statements of Cash Flows**  
(unaudited)

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (37,065)	\$ (4,282,515)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	312,078	335,743
Gain on sale of supplies	(95,000)	-
Stock-based compensation	317,532	514,623
Changes in operating assets and liabilities:		
Accounts receivable	(2,724,750)	(337,178)
Prepaid expenses and other assets	132,927	76,622
Accounts payable	204,621	(54,339)
Accrued expenses and other liabilities	(497,120)	(451,500)
Deferred revenues	(644,137)	(416,668)
Net cash used in operating activities	(3,030,914)	(4,615,212)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Sale of supplies	95,000	-
Purchases of property and equipment	-	(3,840)
Net cash provided by (used in) investing activities	95,000	(3,840)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payments on capital lease obligations	(47,251)	(66,743)
Proceeds from sale of common stock and warrants	2,792,676	-
Net cash provided by (used in) financing activities	2,745,425	(66,743)
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(190,489)</b>	<b>(4,685,795)</b>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<b>4,378,662</b>	<b>9,421,770</b>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<b>\$ 4,188,173</b>	<b>\$ 4,735,975</b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 4,701	\$ 10,494
Unrealized gain (loss) on available-for-sale investments	\$ 27,023	\$ (59)

The accompanying notes are an integral part of these consolidated 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 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. 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 bremelanotide and PL-6983, peptide melanocortin receptor agonists for treatment of sexual dysfunction, and PL-3994, an agonist peptide mimetic which binds to natriuretic peptide receptor A for treatment of heart failure. The Company has an exclusive global 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.

Key elements of the Company's business strategy include using its technology and expertise to develop and commercialize therapeutic products; entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates the Company is developing; partially funding its development and discovery programs with the cash flow from the Company's AstraZeneca collaboration agreement and any future agreements with other companies; and, depending on the availability of sufficient funding, expanding the Company's pipeline by using its expertise in drug discovery technologies for melanocortin and natriuretic peptide receptor systems and acquiring 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, 2009 and incurred a net loss for the three months ended September 30, 2009. 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.

In August 2009, the Company sold 9,484,848 units in a registered direct offering for gross proceeds of \$3,130,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 shares of common stock at an exercise price of \$0.33 per share. Net proceeds to the Company, after offering costs, were approximately \$2,800,000. The placement agent was also provided with a warrant to purchase 474,242 shares of common stock at an exercise price of \$0.41 per share exercisable through November 27, 2012.

In September 2009, the Company and AstraZeneca amended the collaboration agreement, which provides for \$5,000,000 in payments to the Company, with an initial payment of \$2,500,000 payable within 30 days of signing and the balance payable in the first quarter of calendar 2010.

The Company believes that its cash, cash equivalents, accounts receivable and available-for-sale investments as of September 30, 2009, together with the additional receipts from the September 2009 amendment to our AstraZeneca agreement and other income, are adequate to fund operations through at least September 30, 2010. 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, 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.

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

*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, 2009 consists primarily of amounts due from AstraZeneca. For the three months ended September 30, 2009 and 2008, 100% of revenues were from AstraZeneca.

### (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, 2009, and its results of operations and its cash flows for the three months ended September 30, 2009 and 2008. The results of operations for the three-month period ended September 30, 2009 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, 2010.

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, 2009, filed with the Securities and Exchange Commission (SEC), which includes consolidated financial statements as of June 30, 2009 and 2008 and for each of the fiscal years in the three-year period ended June 30, 2009.

### (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 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 and computer 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

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

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-Based Compensation* The Company charges to expense the fair value of stock options and similar awards granted. 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. The Company has recorded a valuation allowance against its deferred tax assets based on the history of losses incurred.

*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. For the three months ended September 30, 2009 and 2008, there were no dilutive effects of such securities as the Company incurred a net loss in each period. Common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding option and warrants and the vesting of restricted stock units amounted to an aggregate of 19,267,487 and 15,754,226 shares as of September 30, 2009 and 2008, respectively.

*Subsequent Events* The Company has evaluated subsequent events through November 13, 2009.

*Recently Issued Accounting Pronouncements* In June 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Codification 105-10 (formerly Statement of Financial Accounting Standards 168), The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, which was effective for the Company beginning July 1, 2009. The Financial Accounting Standards Board Accounting Standards Codification (the Codification) officially became the single source of authoritative nongovernmental generally accepted accounting principles (GAAP), superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force and related accounting literature. After that date, only one level of authoritative GAAP exists. All other accounting literature is considered non-authoritative. The Codification reorganizes the thousands of GAAP pronouncements into roughly 90 accounting topics and displays them using a consistent structure. Also included in the Codification is relevant SEC guidance organized using the same topical structure in separate sections within the Codification. The Company adopted this statement and has updated its existing GAAP references to the new codification.

---

### Table of Contents

#### **(4) AGREEMENT WITH ASTRAZENECA:**

In January 2007, the Company entered into an exclusive global licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

syndrome. In June 2008, the collaboration agreement was amended to include additional compounds and associated intellectual property developed by the Company. In December 2008, the collaboration agreement was further amended to include additional compounds and associated intellectual property developed by the Company and extended the research collaboration for an additional year through January 2010. In September 2009, the collaboration agreement was further amended to modify royalty rates and milestone payments. The collaboration is based on the Company's melanocortin receptor obesity program and includes access to compound libraries, core technologies and expertise in melanocortin receptor drug discovery and development.

In December 2008, the Company also entered into a clinical trial sponsored research agreement with AstraZeneca, under which the Company agreed to conduct a study of the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters. Under the terms of the clinical trial agreement, AstraZeneca will pay all costs associated with the study. The Company recognized \$122,091 as revenue in the three months ended September 30, 2009 under the clinical trial sponsored research agreement. As part of the September 2009 amendment to the collaboration agreement, the Company agreed to conduct additional studies on the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters.

The Company received a \$10,000,000 up-front payment from AstraZeneca on execution of the collaboration agreement. Under the September 2009 amendment the Company will be paid an additional \$5,000,000 in consideration of reduction of future milestones and royalties and providing specified materials to AstraZeneca. The Company is now eligible for milestone payments totaling up to \$145,250,000, with up to \$85,250,000 contingent on development and regulatory milestones and the balance contingent on achievement of sales targets. In addition, the Company will receive royalties on sales of any approved products. AstraZeneca assumed responsibility for product commercialization, product discovery and development costs, with both companies contributing scientific expertise in the research collaboration. The Company is providing research services to AstraZeneca through January 2010 at a contractual rate per full-time-equivalent employee.

The Company has determined that the license agreement and research services should be evaluated together as a single unit for purposes of revenue recognition. Accordingly, the aggregate payments of \$15,000,000 are being recognized as revenue on a straight-line basis over the period during which the Company may perform research services under the agreement. The Company must continually evaluate the estimated remaining performance period, and has revised the estimated performance period to end January 2010 based on the September 2009 amendment. For the three months ended September 30, 2009 and 2008 the Company recognized as revenue \$2,694,137, and \$416,667, respectively, related to the payments. Per-employee compensation from AstraZeneca for research services is recognized as earned at the contractual rate, which approximates the fair value of such services. Revenue recognized for research services for the three months ended September 30, 2009 and 2008 were \$846,391 and \$337,178, respectively.

### (5) INVESTMENTS:

The following table summarizes investments at September 30, 2009 and 2008:

	September 30, 2009	June 30, 2009
Cost	\$ 3,323,539	\$ 3,323,539
Gross unrealized gains	143,193	116,170
Gross unrealized losses	(59)	(59)
 Total available-for-sale investments	 \$ 3,466,673	 \$ 3,439,650

The fair value of investments are classified using a hierarchy prioritized based on inputs. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are 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.

---

### Table of Contents

financial asset or liability's classification 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 carried at fair value as of September 30, 2009:

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

	Fair Value	Quoted prices in active markets (Level 1)	Quoted prices in active markets (Level 2)	Quoted prices in active markets (Level 3)
Mutual Funds	\$ 3,466,673	\$ 3,466,673	\$ -	\$ -

**(6) COMPREHENSIVE LOSS:**

Comprehensive loss consists of the following:

	Three Months Ended September 30,	
	2009	2008
Net loss	\$ (37,065 )	\$ (4,282,515 )
Unrealized gain (loss) on available-for-sale investments	27,023	(59 )
Comprehensive loss	\$ (10,042 )	\$ (4,282,574 )

**(7) STOCKHOLDERS' EQUITY:**

In August 2009, the Company sold 9,484,848 units in a registered direct offering for gross proceeds of \$3.1 million. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 shares of common stock at an exercise price of \$0.33 per share. Net proceeds to the Company, after costs of the offering, were \$2.8 million. In addition, the Company issued to the placement agent warrants to purchase 474,242 shares at an exercise price of \$0.41 per share.

**(8) OTHER INCOME:**

In September 2009, the Company sold supplies for gross proceeds of \$95,000. The supplies were previously charged to expense on the statement of operations. The total gain of \$95,000 is included on the statement of operations for the three months ended September 30, 2009.

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 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, 2009 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. and subsidiary.

## 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, 2009, and have not changed as of September 30, 2009. 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 agonist compounds with a focus on melanocortin and natriuretic peptide receptor systems. We have a diverse pipeline of active development programs targeting melanocortin and natriuretic receptors, including development of proposed products for treatment of heart failure, sexual dysfunction, obesity, diabetes and metabolic syndrome.

We currently have the following active drug development programs:

Bremelanotide, a peptide melanocortin receptor agonist, for treatment of sexual dysfunction, targeting female sexual dysfunction (FSD) and erectile dysfunction (ED) in patients non-responsive to current therapies.

PL-6983, a peptide melanocortin receptor agonist, for treatment of sexual dysfunction.

PL-3994, a peptide mimetic natriuretic peptide receptor A (NPRA) agonist, for treatment of heart failure (HF).

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

Key elements of our business strategy include: using our technology and expertise to develop and commercialize therapeutic products; 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 AstraZeneca collaboration agreement and any future agreements with other companies; 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.

---

## Table of Contents

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, 2009 Compared to the Three Months Ended September 30, 2008*

**Revenue** - For the three months ended September 30, 2009, we recognized \$3.7 million in revenue pursuant to our license agreement with AstraZeneca, compared to \$0.7 million for three months ended September 30, 2008.

Revenue for the three months ended September 30, 2009 and 2008 consisted of \$1.0 million and \$0.3 million, respectively, related to our research services performed during those periods, and \$2.7 million and \$0.4 million, respectively, of revenue related to AstraZeneca's up-front license fee. The increase in revenue relating to AstraZeneca's up-front license fee is related to revision of the period during which we may perform research services for purposes of revenue recognition. Currently, the research services obligation under our agreement with AstraZeneca expires in January 2010. There were no substantive development activities on our NeutroSpec program during the three months ended September 30, 2009 and 2008, and we do not anticipate any substantive development activities on the NeutroSpec program in the fiscal year

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

ending June 30, 2010, though the agreement with Mallinckrodt has not been terminated. 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 development milestones.

*Research and Development* - Research and development expenses decreased to \$2.7 million for the three months ended September 30, 2009 from \$3.7 million for the three months ended September 30, 2008. The decrease is the result of the restructuring of our clinical-stage product portfolio and development programs.

Research and development expenses related to our bremelanotide, PL-3994, PL-6983, obesity, NeutroSpec and other preclinical programs were \$0.5 million for the three months ended September 30, 2009 compared to \$1.1 million for the three months ended September 30, 2008. Spending to date has been primarily related to the identification and optimization of lead compounds, and secondarily to a study of the effects of melanocortin receptor-specific compounds on food intake, obesity and other metabolic parameters and preclinical studies and a Phase 1 trial with subcutaneously administered bremelanotide. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the availability of funds to support future development activities, success of our clinical trials and preclinical and discovery programs, and our ability to progress compounds in addition to bremelanotide and PL-3994 into human clinical trials.

The historical amounts of project spending above exclude general research and development spending, which decreased to \$2.2 million for three months ended September 30, 2009 compared to \$2.6 million for three months ended September 30, 2008. The decrease is primarily related to management's refinement of operations and expense control.

Cumulative spending from inception to September 30, 2009 on our bremelanotide, NeutroSpec and other programs (which includes PL-3994, PL-6983, obesity, and other discovery programs) amounts to approximately \$127.6 million, \$55.5 million and \$52.8 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 larger-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, net cash inflows will be generated.

*General and Administrative* - General and administrative expenses decreased to \$1.2 million for the three months ended September 30, 2009 compared to \$1.5 million for the three months ended September 30, 2008. The decrease is primarily related to management's refinement of operations and expense control.

---

### Table of Contents

#### **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 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 and require us to curtail or cease certain programs or our operations.

During the three months ended September 30, 2009, we used \$3.0 million of cash for our operating activities, compared to \$4.6 million used in the three months ended September 30, 2008. Lower cash outflows from operations in the three months ended September 30, 2009 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.

During the three months ended September 30, 2009, cash provided by investing activities of \$0.1 million consisted solely of the sale of supplies. During the three months ended September 30, 2008, cash used in investing activities consisted of \$4,000 for the purchase of equipment.

During the three months ended September 30, 2009, cash provided by financing activities was \$2.7 million, consisting of payments on capital lease obligations offset by net proceeds of approximately \$2.8 million from the sale of 9,484,848 units in a registered direct offering. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 shares of common stock at an exercise price of \$0.33 per share.

In September 2009, we signed an amendment to our collaboration agreement with AstraZeneca which provides for \$5.0 million in payments to us, with an initial payment of \$2.5 million payable within 30 days of signing and the balance payable in the first quarter of calendar 2010.

As of September 30, 2009, our cash and cash equivalents were \$4.2 million, our available-for-sale investments were \$3.5 million and our accounts receivable were \$3.2 million (including \$2.5 million referenced above). We believe that these amounts, together with the additional receipts from the September 2009 amendment to our AstraZeneca agreement and other income, are adequate to fund operations through at least September 30, 2010. We will need additional funds to continue development of bremelanotide, PL-3994 and PL-6983, as well as our early stage research and discovery programs, and to fund operations after that date.

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. 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 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. 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 may also be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available, and

---

### Table of Contents

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.

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.**

Not required to be provided by smaller reporting companies.



**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.

13

---

Table of Contents

**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, 2009.

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

On August 17, 2009, in connection with the closing of our registered direct offering of common stock and warrants to purchase common stock, we issued to Rodman & Renshaw, LLC or its permitted designees, as partial consideration for its services as placement agent, warrants to purchase up to 474,242 shares of our common stock at an exercise price of \$0.41 per share. The warrants are exercisable at the option of the holder at any time beginning on issuance through and including December 27, 2012. These warrants were offered and sold by us in reliance upon exemptions from the registration statement requirements by Section 4(2) of the Securities Act of 1933, as amended.

**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:

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-Q

- 10.1 Third Amendment dated September 24, 2009 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request. \*
- 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. \*

---

\* Exhibit filed with this report.

Table of Contents

**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 13, 2008

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

Date: November 13, 2008

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

Table of Contents

**EXHIBIT INDEX**

- 10.1 Third Amendment dated September 24, 2009 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request. \*
- 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. \*

---

\* Exhibit filed with this report.