

PALATIN TECHNOLOGIES INC  
Form 10-Q  
November 14, 2012

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**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, 2012

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.**

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(Exact name of registrant as specified in its charter)

Delaware 95-4078884  
(State or other jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

**4B Cedar Brook Drive** 08512  
**Cranbury, New Jersey**  
(Address of principal executive offices) (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 S 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 S 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 S  
(Do not check if a smaller reporting company)

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

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As of November 12, 2012, 38,947,912 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

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**PALATIN TECHNOLOGIES, INC.**

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**PART I - FINANCIAL INFORMATION****Item 1. Financial Statements****PALATIN TECHNOLOGIES, INC.****and Subsidiary****Consolidated Balance Sheets**

(unaudited)

|  | September 30,<br>2012 | June 30, 2012 |
|--|-----------------------|---------------|
| <b>ASSETS</b>  |                       |               |
| Current assets:  |                       |               |
| Cash and cash equivalents  | \$33,461,066          | \$3,827,198   |
| Accounts receivable  | 31,437                | 27,631        |
| Restricted cash  | —                     | 350,000       |
| Prepaid expenses and other current assets  | 851,844               | 532,010       |
| Total current assets   | 34,344,347            | 4,736,839     |
| Property and equipment, net  | 299,735               | 318,653       |
| Other assets   | 58,748                | 324,992       |
| Total assets   | \$34,702,830          | \$5,380,484   |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                       |               |
| Current liabilities:   |                       |               |
| Capital lease obligations  | \$22,707              | \$22,277      |
| Accounts payable   | 321,621               | 294,894       |
| Accrued expenses   | 1,285,215             | 2,706,496     |
| Accrued compensation   | —                     | 433,333       |
| Total current liabilities  | 1,629,543             | 3,457,000     |
| Capital lease obligations  | 14,068                | 19,909        |
| Deferred rent  | 63,372                | 72,677        |
| Total liabilities  | 1,706,983             | 3,549,586     |
| Stockholders' equity:  |                       |               |
| Preferred stock of \$0.01 par value – authorized 10,000,000 shares; Series A<br>Convertible; issued and outstanding 4,697 shares as of September 30, 2012 and<br>4,997 as of June 30, 2012 | 47                    | 50            |

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|  |               |               |
|--|---------------|---------------|
| Common stock of \$0.01 par value – authorized 200,000,000 shares; issued and outstanding 38,947,912 shares as of September 30, 2012 and 34,900,591 as of June 30, 2012, respectively | 389,479       | 349,006       |
| Additional paid-in capital   | 282,302,585   | 240,725,127   |
| Accumulated deficit  | (249,696,264) | (239,243,285) |
| Total stockholders' equity   | 32,995,847    | 1,830,898     |
| Total liabilities and stockholders' equity   | \$34,702,830  | \$5,380,484   |

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

**PALATIN TECHNOLOGIES, INC.****and Subsidiary****Consolidated Statements of Operations**

(unaudited)

|  | Three Months Ended<br>September 30, |                |
|--|-------------------------------------|----------------|
|  | 2012                                | 2011           |
| REVENUES:  | \$3,806                             | \$27,217       |
| OPERATING EXPENSES:  |                                     |                |
| Research and development   | 2,343,313                           | 2,284,383      |
| General and administrative   | 1,061,016                           | 1,109,382      |
| Total operating expenses   | 3,404,329                           | 3,393,765      |
| Loss from operations   | (3,400,523 )                        | (3,366,548 )   |
| OTHER INCOME (EXPENSE):  |                                     |                |
| Investment income  | 14,371                              | 15,040         |
| Interest expense   | (2,282 )                            | (2,973 )       |
| Increase in fair value of warrants   | (7,069,165 )                        | —              |
| Gain on disposition of supplies and equipment  | 4,620                               | —              |
| Total other income (expense), net  | (7,052,456 )                        | 12,067         |
| NET LOSS   | \$(10,452,979)                      | \$(3,354,481 ) |
| Basic and diluted net loss per common share  | \$(0.15 )                           | \$(0.10 )      |
| Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share | 71,669,170                          | 34,900,591     |

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

**PALATIN TECHNOLOGIES, INC.****and Subsidiary****Consolidated Statements of Cash Flows**

(unaudited)

|   | Three Months Ended<br>September 30, |                     |
|---|-------------------------------------|---------------------|
|   | 2012                                | 2011                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                                     |                     |
| Net loss  | \$(10,452,979)                      | \$(3,354,481 )      |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                     |                     |
| Depreciation and amortization   | 27,467                              | 255,002             |
| Gain on sale of supplies and equipment                                      | (4,620 )                            | —                   |
| Stock-based compensation  | 176,103                             | 210,273             |
| Increase in fair value of warrants  | 7,069,165                           | —                   |
| Changes in operating assets and liabilities:                                |                                     |                     |
| Accounts receivable   | (3,806 )                            | 131,149             |
| Prepaid expenses, restricted cash and other assets                          | 296,410                             | (41,397 )           |
| Accounts payable  | 26,727                              | (160,702 )          |
| Accrued expenses, compensation and deferred rent                            | (1,863,919 )                        | (988,397 )          |
| Unearned revenue  | —                                   | (27,217 )           |
| Net cash used in operating activities                                       | (4,729,452 )                        | (3,975,770 )        |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                                     |                     |
| Proceeds from sale of supplies and equipment                                | 4,620                               | —                   |
| Purchases of property and equipment   | (8,550 )                            | —                   |
| Net cash used in investing activities                                       | (3,930 )                            | —                   |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                                     |                     |
| Payments on capital lease obligations                                       | (5,411 )                            | (10,256 )           |
| Payment of withholding taxes related to restricted stock units              | (34,785 )                           | —                   |
| Proceeds from sale of common stock units                                    | 34,407,446                          | —                   |
| Net cash provided by (used in) financing activities                         | 34,367,250                          | (10,256 )           |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>                 | <b>29,633,868</b>                   | <b>(3,986,026 )</b> |
| CASH AND CASH EQUIVALENTS, beginning of year                                | 3,827,198                           | 18,869,639          |
| CASH AND CASH EQUIVALENTS, end of year                                      | \$33,461,066                        | \$14,883,613        |
| <b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>                                  |                                     |                     |
| Cash paid for interest  | \$2,013                             | \$2,973             |



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

**PALATIN TECHNOLOGIES, INC.**

**and Subsidiary**

**Notes to Consolidated Financial Statements**

(unaudited)

**(1) ORGANIZATION:**

*Nature of Business* – Palatin Technologies, Inc. (Palatin or the Company) is a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Palatin’s programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. 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, pigmentation disorders 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 acute asthma, heart failure, hypertension and other cardiovascular diseases.

The Company’s primary product in development is bremelanotide for the treatment of female sexual dysfunction (FSD). The Company also has drug candidates or development programs for obesity, erectile dysfunction, pulmonary diseases, cardiovascular diseases and inflammatory diseases. The Company has an exclusive global research collaboration and license agreement with AstraZeneca AB (AstraZeneca) to commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome, with drug candidates in preclinical evaluation.

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 that the Company is developing; and partially funding its product candidate development programs with the cash flow generated from the Company’s license agreements with AstraZeneca and any other companies.

*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, 2012 and incurred a net loss for the three months ended September 30, 2012. 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 discussed in Note 6, on July 3, 2012, the Company closed on a \$35,000,000 private placement. The offering consisted of the sale of 3,873,000 shares of the Company's common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of the Company's common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of the Company's common stock. The net proceeds to the Company after deducting the offering expenses were \$34,407,446.

As of September 30, 2012, the Company's cash and cash equivalents were \$33.5 million. The Company intends to utilize existing capital resources for general corporate purposes and working capital, including its clinical trial program with bremelanotide for FSD, preclinical and clinical development of its peptide melanocortin receptor-1 program, preclinical and clinical development of its PL-3994 program and preclinical and clinical development of other portfolio products.

Management believes that the Company's existing capital resources will be adequate to fund its currently planned operations, including completing analysis of results of the Company's Phase 2B clinical trial with bremelanotide for FSD and submitting an end-of-phase 2 meeting request to the U.S. Food and Drug Administration (FDA), through at least calendar year 2013. Phase 3 clinical trials of bremelanotide for FSD, which will not commence before calendar year 2013, will require significant additional resources and capital to complete.

*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. The Company's cash and cash equivalents are primarily invested in one money market fund sponsored by a large financial institution. For the three months ended September 30, 2012 and 2011, 100% of revenues were from AstraZeneca.

**PALATIN TECHNOLOGIES, INC.**

**and Subsidiary**

**Notes to Consolidated Financial Statements**

(unaudited)

**(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, 2012, and its results of operations and its cash flows for the three months ended September 30, 2012 and 2011. The results of operations for the three months ended September 30, 2012 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, 2013.

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, 2012, filed with the Securities and Exchange Commission (SEC), which includes consolidated financial statements as of June 30, 2012 and 2011 and for each of the fiscal years in the three-year period ended June 30, 2012.

**(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. Cash equivalents consist of \$32,980,347 and \$3,344,146 in a money market fund at September 30, 2012 and June 30, 2012, respectively.

*Fair Value of Financial Instruments* – The Company's financial instruments consist primarily of cash equivalents, 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 the short-term nature of these 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 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.

**PALATIN TECHNOLOGIES, INC.**

**and Subsidiary**

**Notes to Consolidated Financial Statements**

(unaudited)

*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. Revenue from grants is recognized as the Company provides the services stipulated in the underlying grants based on the time and materials incurred.

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

*Stock-Based Compensation* – The Company charges to expense the fair value of stock options and other equity 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 and diluted earnings per common share (EPS) are calculated in accordance with the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 260, “Earnings per Share.” The Series A 2012 warrants and Series B 2012 warrants, issued in connection with the July 3, 2012 private placement offering, are exercisable for nominal consideration and therefore, are to be considered in the computation of basic and diluted net loss per common share. The Series A 2012 warrants to purchase up to 31,988,151 shares of common stock are exercisable starting at July 3, 2012 and therefore, are included in the weighted average number of common shares outstanding used in computing basic and diluted net loss per common share starting on July 3, 2012.

The Series B 2012 warrants to purchase up to 35,488,380 shares of common stock were considered contingently issuable shares and were not included in computing basic net loss per common share until the Company received stockholder approval for the increase in authorized underlying common stock on September 27, 2012 (see note 6). For diluted EPS, contingently issuable shares are to be included in the calculation as of the beginning of the period in which the conditions were satisfied, unless the effect would be anti-dilutive. The Series B 2012 warrants have been excluded from the calculation of diluted net loss per common share during the period from July 3, 2012 until September 27, 2012 as the impact would be anti-dilutive.

As of September 30, 2012 and 2011, common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding options and warrants (excluding the Series A 2012 and Series B 2012 warrants), and the vesting of restricted stock units amounted to an aggregate of 27,904,284 and 27,127,955 shares, respectively. These share amounts have been excluded from the calculation of net loss per share as the impact would be anti-dilutive.

**(4) AGREEMENT WITH ASTRAZENECA:**

In January 2007, the Company entered into an exclusive global research collaboration and license agreement with AstraZeneca to discover, develop and commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome. In June 2008, the license agreement was amended to include additional compounds and associated intellectual property developed by the Company. In December 2008, the license 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 license 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. As part of the September 2009 amendment to the research collaboration and license agreement, the Company agreed to conduct additional studies on the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters.

**PALATIN TECHNOLOGIES, INC.**

**and Subsidiary**

**Notes to Consolidated Financial Statements**

(unaudited)

In December 2009 and 2008, the Company also entered into clinical trial sponsored research agreements with AstraZeneca, under which the Company agreed to conduct studies of the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters. Under the terms of these clinical trial agreements, AstraZeneca paid \$5,000,000 as of March 31, 2009 upon achieving certain objectives and paid all costs associated with these studies. The Company recognized \$3,806 and \$27,217, respectively, as revenue in the three months ended September 30, 2012 and 2011 under these clinical trial sponsored research agreements.

The Company received an up-front payment of \$10,000,000 from AstraZeneca on execution of the research collaboration and license agreement. Under the September 2009 amendment the Company was paid an additional \$5,000,000 in consideration of reduction of future milestones and royalties and providing specific 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 is eligible to receive mid to high single digit 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 provided research services to AstraZeneca through January 2010, the expiration of the research collaboration portion of the research collaboration and license agreement, at a contractual rate per full-time-equivalent employee.

**(5) FAIR VALUE MEASUREMENTS:**

The fair value of cash equivalents 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. A 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:

|                     | Fair Value   | Quoted prices in active markets (Level 1) | Other quoted/observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
|---------------------|--------------|---|--|---|
| September 30, 2012: |              |   |  |   |
| Money Market Fund   | \$32,980,347 | \$32,980,347                              | \$ —                                     | \$ —                                      |
| June 30, 2012:      |              |   |  |   |
| Money Market Fund   | \$3,344,146  | \$3,344,146                               | \$ —                                     | \$ —                                      |

**(6) STOCKHOLDERS' EQUITY:**

*Common Stock Transactions* -On July 3, 2012, the Company closed on a private placement offering in which the Company sold, for aggregate proceeds of \$35,000,000, 3,873,000 shares of its common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of common stock. The Series A 2012 warrants are exercisable starting July 3, 2012 at an exercise price of \$0.01 per share, and expire ten years from the date of issuance. The Series B 2012 warrants are exercisable starting September 27, 2012, the date the Company's stockholders increased the number of its authorized shares of common stock, at an exercise price of \$0.01 per share, and expire September 27, 2022. The holders may exercise the warrants on a cashless basis. The warrants are subject to a blocker provision prohibiting exercise of the warrants if the holder and its affiliates would beneficially own in excess of 9.99% of the total number of shares of common stock of the Company following such exercise (as may be adjusted to the extent set forth in the warrant). The warrants also provide that in the event of a Company Controlled Fundamental Transaction (as defined in the warrants), the Company may, at the election of the warrant holder, be required to redeem all or a portion of the warrants at an amount tied to the greater of the then market price of the Company's common stock or the amount per share paid to any other person.

**PALATIN TECHNOLOGIES, INC.**

**and Subsidiary**

**Notes to Consolidated Financial Statements**

(unaudited)

Because there were not sufficient authorized shares to cover all the outstanding Series B 2012 warrants in the private placement offering as of closing, under ASC 815, "Derivatives and Hedging," the portion of the warrants above the then authorized level of common stock was required to be classified as a liability and carried at fair value on the Company's balance sheet. The fair value was calculated by multiplying the number of shares underlying the Series B 2012 warrants above the then authorized level of the Company's common stock by the closing price of its common stock less the exercise price of \$0.01 per share. The warrants were liability classified through September 27, 2012, at which time the then fair value of the warrant liability was reclassified into stockholders' equity upon stockholder approval of the increase in authorized common stock. The increase in fair value, as a result of the Company's common stock increasing from \$0.50 per share at date of issuance to \$0.71 per share upon shareholder approval, of \$7,069,165 has been recorded as a non-operating expense.

The purchase agreement for the private placement provides that the purchasers, funds under the management of QVT Financial LP, have certain rights until July 3, 2018, including rights of first refusal and participation in any subsequent equity or debt financing, provided that the funds own at least 20% of the outstanding common stock of the Company calculated as if warrants held by the funds were exercised. The purchase agreement also contains certain restrictive covenants so long as the funds continue to hold specified amounts of warrants or beneficially own specified amounts of the outstanding shares of common stock.

The net proceeds to the Company were \$34,407,446, after deducting offering expenses payable by the Company and excluding the proceeds to the Company, if any, from the exercise of the warrants issued in the offering.

*Stock Options* – In July 2012, the Company granted 285,000 options to its executive officers, 182,500 options to its employees and 112,500 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company will amortize the fair value of these options of \$182,000, \$108,000 and \$72,000, respectively, over the 48 months ending July 2016. The Company recognized \$35,188 of stock-based compensation expense related to these options during the three months ended September 30, 2012.

*Restricted Stock Units* – In July 2012, the Company granted 222,500 restricted stock units to its executive officers under the Company’s 2011 Stock Incentive Plan. The Company will amortize the fair value of these restricted stock units of \$160,000 over the 24 months ending July 2014. The Company recognized \$24,547 of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2012.

In June 2011, the Company granted 500,000 restricted stock units to its executive management under the Company’s 2011 Stock Incentive Plan. Half of these restricted stock units vested on June 22, 2012 and the remainder vests 24 months from the date of grant. The grant date fair value of these restricted stock units of \$430,000 is being amortized over the 24 month vesting period of the award. The Company recognized \$26,875 and \$80,625 of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2012 and 2011.

Stock-based compensation cost for the three months ended September 30, 2012 and 2011 for stock options and equity-based instruments issued other than the stock options and restricted stock units described above was \$89,493 and \$129,648, respectively.

## **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 and the audited consolidated financial statements and notes thereto included in our annual report on Form 10-K for the year ended June 30, 2012.

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, ability to raise capital or repay debt, if required, clinical trials and results, uncertainties associated with product research and development, product plans and performance, management's assessment of market factors, as well as statements regarding our strategy and plans and those of 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, 2012 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 its 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, 2012, have not changed as of September 30, 2012. 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 developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is bremelanotide for the treatment of female sexual dysfunction (FSD). In addition, we have drug candidates or development programs for obesity, erectile dysfunction, pulmonary diseases, cardiovascular diseases and inflammatory diseases.

The following drug development programs are actively under development:

- Bremelanotide, a peptide melanocortin receptor agonist, for treatment of FSD. This drug candidate has completed a Phase 2B clinical trial, and we have announced top-line results.
- Melanocortin receptor-based compounds for treatment of obesity, under development by AstraZeneca AB (AstraZeneca) pursuant to our research collaboration and license agreement.
- PL-3994, a peptide mimetic natriuretic peptide receptor A (NPR-A) agonist, for treatment of cardiovascular and pulmonary indications.

The following chart shows the status of our drug development programs.

|                          | Program                 | Indication   | Preclinical | Phase 1 | Phase 2 | Phase 3 |
|--------------------------|-------------------------|--|-------------|---------|---------|---------|
|                          | Bremelanotide           | Female Sexual Dysfunction                          |             |         |         |         |
|                          | Melanocortin Receptor   | Obesity and Diabetes                               |             |         |         |         |
| <b>Programs</b>          | Next Generation Peptide | Female Sexual Dysfunction and Erectile Dysfunction |             |         |         |         |
|                          | Natriuretic Peptide     | Cardiovascular Indications                         |             |         |         |         |
| <b>Receptor Programs</b> | PL-3994                 | Pulmonary Indications                              |             |         |         |         |

On November 8, 2012, we reported positive top-line results, including the successful achievement of statistical significance for the primary endpoint and key secondary endpoints in our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for treatment of FSD. The primary endpoint data analysis of 327 pre-menopausal women with female sexual arousal disorder (FSAD), hypoactive sexual desire disorder (HSDD), or a combination of both disorders, the most common types of FSD, demonstrate that women taking bremelanotide showed statistically significant increases in the number of Satisfying Sexual Events (SSEs) and also showed statistically significant improved measures of overall sexual functioning and distress related to sexual dysfunction, compared to placebo. Bremelanotide was well-tolerated during the trial. The most common types of treatment-emergent adverse events reported more frequently in the bremelanotide arms were facial flushing, nausea and emesis, which were mainly mild-to-moderate in severity. Adverse events that most commonly led to discontinuation were nausea and emesis. No serious adverse events were attributable to bremelanotide during the trial. Based on the results of discussions with the FDA and external advisors regarding the results of this trial and further development steps, Phase 3 activities are anticipated to start in the second-half of calendar year 2013.

We have initiated preclinical studies with new peptide drug candidates for a number of indications, primarily inflammatory disease related, and are continuing preclinical development with a next generation peptide for FSD and erectile dysfunction.

On July 3, 2012, we closed on a private placement of 3,873,000 shares of our common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of our common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of our common stock. Aggregate gross proceeds to us were \$35,000,000, with net proceeds, after deducting offering expenses, of \$34,407,446.

On September 27, 2012, at a special meeting our stockholders voted to increase our authorized common stock from 100,000,000 to 200,000,000 shares, and we filed a certificate of amendment with the Secretary of State of Delaware the same day. This satisfied certain contractual obligations relating to the Series B 2012 warrants in our 2012 private placement, so that interest will not be payable on the value of the Series B 2012 warrants and we will not be required to redeem the Series B 2012 warrants for failure to increase the number of authorized shares.

Key elements of our business strategy include: using our technology and expertise to develop and commercialize innovative therapeutic products; entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing; and, partially funding our product development programs with the cash flow generated from our license agreement with AstraZeneca and any other companies.

We incorporated in Delaware in 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B 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, proxy statements, 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), Section 14A 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 are not incorporated into this quarterly report on Form 10-Q.

## **Results of Operations**

### *Three Months Ended September 30, 2012 Compared to the Three Months Ended September 30, 2011*

*Revenue* – For the three months ended September 30, 2012, we recognized \$3,806 in revenue compared to \$27,217 for the three months ended September 30, 2011 pursuant to our license agreement with AstraZeneca. Revenue for the three months ended September 30, 2012 and 2011 consisted entirely of reimbursement of development costs and per-employee compensation, earned at the contractual rate.

*Research and Development* – Research and development expenses were \$2.3 million for the three months ended September 30, 2012 and September 30, 2011. These expenses are primarily costs relating to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. We are currently compiling and analyzing data from this Phase 2B clinical trial, which commenced in June 2011 and had the last patient complete treatment in September 2012.

Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonist, obesity and other preclinical programs were \$1.7 million for the three months ended September 30, 2012 compared to \$1.3 million for the three months ended September 30, 2011. Spending to date has been primarily related to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. 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 amounts of project spending above exclude general research and development spending, which decreased to \$0.6 million for the three months ended September 30, 2012 compared to \$1.0 million for the three months ended September 30, 2011. The decrease is the result of reducing staffing levels and closing our research laboratory operations in connection with the lease expiration of our laboratory facilities in July 2012.

Cumulative spending from inception to September 30, 2012 on our bremelanotide, NeutroSpec (a previously marketed imaging product on which all work is suspended) and other programs (which include PL-3994, other peptide melanocortin agonists, obesity and other discovery programs) amounts to approximately \$156.8 million, \$55.6 million and \$59.6 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 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, which consists mainly of compensation and related costs, were \$1.1 million for the three months ended September 30, 2012 and September 30, 2011.

### **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 (GMPs);
- intellectual property rights;
- product introduction;
- marketing, sales and competition; and
- obtaining sufficient capital.

Failure to enter into collaboration agreements and 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.

During the three months ended September 30, 2012, we used \$4.7 million of cash for our operating activities, compared to \$4.0 million used in the three months ended September 30, 2011. Increased net cash outflows from operations in the three months ended September 30, 2012 were primarily the result of costs relating to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD, in which the last patient completed treatment in September 2012. 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, 2012, net cash used in investing activities was \$3,930, consisting of \$4,620 in proceeds from the sale of equipment offset by \$8,550 used for capital expenditures. No cash was either used in or provided by investing activities during the three months ended September 30, 2011.

During the three months ended September 30, 2012, cash provided by financing activities of \$34.4 million consisted primarily of the net proceeds from the completion of a private placement of 3,873,000 shares of our common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of our common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of our common stock. Aggregate gross proceeds to us were \$35,000,000, with net proceeds, after deducting offering expenses, of \$34,407,446. During the three months ended September 30, 2011, cash used in financing activities consisted of payments of \$10,256 on capital lease obligations during the quarter.

As of September 30, 2012, our cash and cash equivalents were \$33.5 million and our current liabilities were \$1.6 million. We believe that our cash and cash equivalents are adequate to fund our planned operations, including completing analysis of results of our Phase 2B clinical trial with bremelanotide for FSD and submitting an end-of-Phase 2 meeting request to the U.S. Food and Drug Administration (FDA), through at least calendar year 2013. Over the next twelve months we intend to focus efforts on preparing for our Phase 3 clinical trial with bremelanotide for FSD, assuming that results of the end-of-Phase 2 meeting with FDA support advancing the program, conducting preclinical research on one or more peptide melanocortin agonists for sexual dysfunction and other indications, conducting preclinical research on peptide melanocortin agonists for inflammatory disease related indications, and development and testing of an inhaled formulation of PL-3994.

Our current cash and cash equivalents are not sufficient to complete all of the clinical trials required for product approval for any of our products. We expect that the Phase 3 bremelanotide clinical trial program for FSD, which will not commence before calendar year 2013, will require significant additional resources and capital to complete. We intend to seek additional capital through public or private equity or debt financings, collaborative arrangements on our product candidates, including bremelanotide for FSD, or other sources. However, sufficient additional funding to support operations past calendar year 2013, including Phase 3 clinical trials with bremelanotide, may not be available on acceptable terms or at all. If additional funding is not available, we will 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 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.

We anticipate incurring additional losses over at least the next few years. To achieve profitability, if ever, 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 as of September 30, 2012. 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.

## **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 claim or legal proceeding.

### **Item 1A. Risk Factors.**

#### **Risks Relating to Our Company**

*We will continue to incur substantial losses over the next few years and we may never become profitable.*

We have never been profitable and we may never become profitable. As of September 30, 2012, we had an accumulated deficit of \$249.7 million. We expect to incur additional losses as we continue our development of bremelanotide, PL-3994 and other product candidates. Unless and until we receive approval from the FDA or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from reimbursements and other contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all.

*We will need to continue to raise funds in the future, and funds may not be available on acceptable terms, or at all.*

As of September 30, 2012, we had cash and cash equivalents of \$33.5 million, with current liabilities of \$1.6 million. We believe we have sufficient currently available working capital to fund our currently planned operations through at least calendar year 2013, but our currently available working capital is not sufficient to complete required clinical trials for any of our product candidates. We will need additional funding to complete required clinical trials and, assuming those clinical trials are successful, as to which there can be no assurance, complete submission of required regulatory applications to the FDA for any of our product candidates. We expect that the Phase 3 bremelanotide clinical trial program for FSD would require significant additional resources and capital to complete.

We do not have any source of significant recurring revenue, and must depend on financing or partnering to sustain our operations. We may raise additional funds through public or private equity financings, debt financings, collaborative arrangements on our product candidates or other sources. However, additional funding may not be available on acceptable terms, or at all. To obtain additional funding, we may need to enter into arrangements that require us to develop only certain of our product candidates or relinquish rights to certain technologies, product candidates and/or potential markets.

If we are unable to raise sufficient additional funds when needed, we may be required to curtail operations significantly, cease clinical trials and further decrease staffing levels. We may seek to license, sell or otherwise dispose of our product candidates, technologies and contractual rights, including rights under our research collaboration and license agreement with AstraZeneca, on the best possible terms available. Even if we are able to license, sell or otherwise dispose of our product candidates, technologies and contractual rights, it is likely to be on unfavorable terms and for less value than if we had the financial resources to develop or otherwise advance our product candidates, technologies and contractual rights ourselves.

***We have a limited operating history upon which to base an investment decision.***

Our operations are primarily focused on acquiring, developing and securing our proprietary technology, conducting preclinical and clinical studies and formulating and manufacturing on a small-scale basis our principal product candidates. These operations provide a limited basis for stockholders to assess our ability to commercialize our product candidates.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our current product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to conduct preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products, or having third parties formulate and manufacture products;
- post-approval monitoring and surveillance of our products;
- conducting sales and marketing activities, either alone or with a partner; and
- obtaining additional capital.

If we are unable to obtain regulatory approval of any of our product candidates, to successfully commercialize any products for which we receive regulatory approval or to obtain additional capital, we may not be able to recover our investment in our development efforts.

***We may not be able to obtain regulatory approval of bremelanotide for FSD even if the product is effective in treating FSD.***

Approval of bremelanotide for treatment of FSD in premenopausal women requires determination by the FDA that the product is both safe and effective. Increases in blood pressure observed in some patients receiving nasally administered bremelanotide was a significant factor leading us to discontinue work on nasally administered bremelanotide for sexual dysfunction. Studies we have conducted with subcutaneously administered bremelanotide suggest that transient elevations of blood pressure are dependent on both the specific patient population and the dose administered. Based on these studies, we believe that bremelanotide will be effective in treating FSD at doses that do not result in unacceptable increases in blood pressure or other unacceptable adverse events. However, results obtained in later phases of clinical trials, including complete analysis of results of our Phase 2B clinical trial for FSD and any future Phase 3 clinical trial, may be inconsistent with results obtained in earlier studies, and may demonstrate an unacceptable safety profile. It is also possible that safety or efficacy results obtained in later phases of clinical trials will be inconclusive. It is not possible to predict, with any assurance, whether the FDA will approve bremelanotide for any indications. The FDA may deny or delay approval of any application for bremelanotide if the FDA determines that the clinical data do not adequately establish the safety of the drug even if efficacy is established. Bremelanotide could take a significantly longer time to obtain approval than we expect and it may never gain approval. If regulatory approval of bremelanotide is delayed or never obtained, our business and our liquidity would be adversely affected.

***Development and commercialization of our product candidates involves a lengthy, complex and costly process, and we may never successfully develop or commercialize any product.***

Our product candidates are at various stages of research and development, will require regulatory approval, and may never be successfully developed or commercialized. Our product candidates will require significant further research, development and testing before we can seek regulatory approval to market and sell them.

We must demonstrate that our product candidates are safe and effective for use in patients in order to receive regulatory approval for commercial sale. Preclinical studies in animals, using various doses and formulations, must be performed before we can begin human clinical trials. Even if we obtain favorable results in the preclinical studies, the results in humans may be different. Numerous small-scale human clinical trials may be necessary to obtain initial data on a product candidate's safety and efficacy in humans before advancing to large-scale human clinical trials. We face the risk that the results of our trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. Adverse or inconclusive results could delay the progress of our development programs and may prevent us from filing for regulatory approval of our product candidates. Additional factors that can cause delay or termination of

our human clinical trials include:

- the availability of sufficient capital to sustain operations and clinical trials;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- the rate of patient enrollment in clinical studies;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

You should evaluate us in light of these uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, as well as unanticipated problems and additional costs relating to:

- product approval or clearance;
- regulatory compliance;
- good manufacturing practices;
- intellectual property rights;
- product introduction; and
- marketing and competition.

*The regulatory approval process is lengthy, expensive and uncertain, and may prevent us from obtaining the approvals we require.*

Government authorities in the United States and other countries extensively regulate the advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation by the FDA and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before a new drug may be marketed in the United States include:

- completion of non-clinical tests including preclinical laboratory and formulation studies and animal testing and toxicology;
- submission to the FDA of an Investigational New Drug application, which must become effective before clinical trials may begin;
- performance of adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a New Drug Application (an NDA);
- FDA review and approval of the NDA before any commercial marketing or sale; and
- Compliance with post-approval commitments and requirements.

Satisfaction of FDA pre-market approval requirements for new drugs typically takes a number of years and the actual time required for approval may vary substantially based upon the type, complexity and novelty of the product or disease. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, the FDA generally has ten months to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical trials is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of the advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. Therefore, our proposed products could take a significantly longer time than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our business and our liquidity would be adversely affected.

Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved by the FDA. Once approved, the FDA may withdraw the product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require



post-marketing studies, referred to as Phase 4 studies, to monitor the approved products in a larger number of patients than were required for product approval and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to seek injunctions, levy fines and civil penalties, criminal prosecution, withdraw approvals and seize products or request recalls.

If regulatory approval of any of our product candidates is granted, it will be limited to certain disease states or conditions. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Outside the United States, our ability to market our product candidates will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process generally includes all of the risks associated with FDA approval described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product to more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficiency has been presented, a marketing authorization will be granted. If we do not obtain, or experience difficulties in obtaining, such marketing authorizations, our business and liquidity may be adversely affected.

***If any approved product does not achieve market acceptance, our business will suffer.***

Regulatory approval for the marketing and sale of any of our product candidates does not assure the product's commercial success. Any approved product will compete with other products manufactured and marketed by major pharmaceutical and other biotechnology companies. The degree of market acceptance of any such product will depend on a number of factors, including:

- perceptions by members of the healthcare community, including physicians, about its safety and effectiveness;
- cost-effectiveness relative to competing products and technologies;
- availability of reimbursement for our products from third party payors such as health insurers, health maintenance organizations and government programs such as Medicare and Medicaid; and
- advantages over alternative treatment methods.

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

***We rely on third parties to conduct clinical trials for our product candidates and their failure to timely perform their obligations could significantly harm our product development.***

We rely on outside scientific collaborators such as researchers at clinical research organizations and universities in certain areas that are particularly relevant to our research and product development plans, such as the conduct of clinical trials and associated tests. There is competition for these relationships, and we may not be able to maintain our relationships with them on acceptable terms. These outside collaborators generally may terminate their engagements with us at any time. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to conduct research on our product candidates and develop them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols or fail to meet expected deadlines, our ability to develop our product candidates and obtain regulatory approval on a timely basis, if at all, may be adversely affected.

***Our drug development programs depend on contract research organizations and other third parties over whom we have no control.***

We have limited research or development staff and do not have dedicated research or development facilities, and depend on third parties, including independent contractors and preclinical contract research organizations, to conduct preclinical studies under agreements with us. These collaborators are not our employees, and we have limited control over the resources that they devote to our programs. These collaborators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. These collaborators generally may terminate their engagements with us at any time. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to conduct research on our product candidates. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these studies fail to comply with agreed protocols or fail to meet expected deadlines, our ability to develop our product candidates and obtain regulatory approval on a timely basis, if at all, may be adversely affected.

***Production and supply of our product candidates depend on contract manufacturers over whom we have no control.***

We do not have the facilities to manufacture bremelanotide, PL-3994, melanocortin receptor agonist compounds or our other potential products. Our contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. Our ability to control third-party compliance with FDA requirements will be limited

to contractual remedies and rights of inspection. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including the FDA's GMPs regulations. Failure of third-party manufacturers to comply with GMPs or other FDA requirements may result in enforcement action by the FDA. Failure to conduct their activities in compliance with FDA regulations could delay our development programs or negatively impact our ability to receive FDA approval of our potential products or continue marketing if they are approved. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

***We have no experience in marketing, distributing and selling products and will substantially rely on our marketing partners to provide these capabilities.***

We are developing bremelanotide for FSD and may develop other melanocortin receptor agonist compounds for sexual dysfunction and other indications and PL-3994 for the treatment of asthma, heart failure and other indications. We do not have marketing partners for any of these products. If any of these products are approved by the FDA or other regulatory authorities, we must either develop marketing, distribution and selling capacity and expertise, which will be costly and time consuming, or enter into agreements with other companies to provide these capabilities. We may not be able to enter into suitable agreements on acceptable terms, if at all.

***We do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.***

Under our research collaboration and license agreement with AstraZeneca for our melanocortin-based therapeutic compounds for obesity, diabetes and related metabolic syndrome, we have no direct control over the development of compounds and have only limited, if any, input on the direction of development efforts. Based on a serious adverse event, AstraZeneca has decided to discontinue development of AZD2820, a subcutaneously-administered peptide melanocortin-4 receptor partial agonist. AstraZeneca has a number of collaboration compounds in various stages of preclinical testing, and remains committed to the continued advancement of melanocortin agonists for treatment of obesity. If the results of further development efforts are negative or inconclusive, AstraZeneca may decide to abandon further development of this program, including terminating the agreement, by giving us notice of termination. Because much of the potential value of the license arrangement with AstraZeneca is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of this license will depend on the efforts of AstraZeneca. If AstraZeneca does not succeed in developing the licensed technology for any reason, or elects to discontinue the development of this program, we may be unable to realize the potential value of this arrangement. Compounds developed during the collaboration phase of our agreement with AstraZeneca are subject to the same payment terms as licensed compounds, but intellectual property relating to collaboration compounds is owned by AstraZeneca. If AstraZeneca does not succeed in developing collaboration compounds, we will not realize any value with respect to those compounds.

*If the market opportunities for bremelanotide and our other products in development are smaller than we anticipate, then our future revenues and business may be adversely affected.*

There are no FDA approved products for treatment of FSD, and thus the size and other parameters relating to the market are not known. The market opportunity for bremelanotide may be smaller than we anticipate. If it is smaller, it may be difficult for us to find marketing partners for bremelanotide, and our ability to generate bremelanotide revenue and business may be adversely affected. This is also true with respect to PL-3994 and other products in development.

*Competing products and technologies may make our proposed products noncompetitive.*

There are other products being developed for FSD, including flibanserin, a continuous-use drug being developed for hypoactive sexual desire disorder. There is competition to develop drugs for treatment of FSD in both premenopausal and postmenopausal patients. Our bremelanotide drug product is intended to be administered by subcutaneous injection, and a drug product for the same indication which utilizes another route of administration, such as a conventional oral drug product, may make subcutaneous bremelanotide noncompetitive.

There are three oral FDA-approved PDE-5 inhibitor drugs for the treatment of ED, other approved products and devices for ED, and other products in development for treatment of ED, including products in clinical trials. There is competition to develop drugs for ED in patients non-responsive to PDE-5 inhibitor drugs, and to develop drugs for treatment of FSD.

There is a large number of products approved for use in asthma, and a number of other products being developed for treatment of acute exacerbations of asthma, including products in clinical trials. There is intense competition to develop drugs for treatment of acute exacerbations of asthma.

We are aware of one recombinant natriuretic peptide product for acutely decompensated congestive heart failure approved and marketed in the United States, and another recombinant natriuretic peptide product approved and marketed in Japan. Clinical trials on other natriuretic peptide products are being conducted in the United States. In addition, other products for treatment of heart failure are either currently being marketed or in development.

The biopharmaceutical industry is highly competitive. We are likely to encounter significant competition with respect to bremelanotide, other melanocortin receptor agonist compounds and PL-3994. Most of our competitors have substantially greater financial and technological resources than we do. Many of them also have significantly greater experience in research and development, marketing, distribution and sales than we do. Accordingly, our competitors

may succeed in developing, marketing, distributing and selling products and underlying technologies more rapidly than we can. These competitive products or technologies may be more effective and useful or less costly than bremelanotide, other melanocortin receptor agonist compounds or PL-3994. In addition, academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and may develop competing products or technologies on their own or through strategic alliances or collaborative arrangements.

***Our ability to achieve revenues from the sale of our products in development will depend, in part, on our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers.***

Our ability to successfully commercialize our products in development will depend, in significant part, on the extent to which we or our marketing partners can obtain reimbursement for our products and also reimbursement at appropriate levels for the cost of our products. Obtaining reimbursement from governmental payers, insurance companies, HMOs and other third-party payers of healthcare costs is a time-consuming and expensive process. There is no guarantee that our products will ultimately be reimbursed. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology and we are not sure whether third-party reimbursement will be available for our proposed products once approved, or that the reimbursement, if obtained, will be adequate. There are no approved products for treating FSD, and thus is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. If we are able to obtain reimbursement, continuing efforts by governmental and third party payers to contain or reduce costs of healthcare may adversely affect our future revenues and ability to achieve profitability. Third-party payers are increasingly challenging the prices charged for diagnostic and therapeutic products and related services. Reimbursement from governmental payers is subject to statutory and regulatory changes, retroactive rate adjustments, administrative rulings and other policy changes, all of which could materially decrease the range of products for which we are reimbursed or the rates of reimbursement by government payers. In addition, recent legislation reforming the healthcare system may result in lower prices or the actual inability of prospective customers to purchase our products in development. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially and adversely affect our ability to operate profitably. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment.

***If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.***

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and
- whether we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

***If we are unable to keep our trade secrets confidential, our technologies and other proprietary information may be used by others to compete against us.***

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws and agreements with our employees and other persons who have access to our proprietary

information. These agreements and arrangements may not provide meaningful protection for our proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

***We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.***

The testing and marketing of medical products entails an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products or cease clinical trials. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently carry liability insurance as to certain clinical trial risks. We, or any corporate collaborators, may not in the future be able to obtain insurance at a reasonable cost or in sufficient amounts, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

***We are highly dependent on our management team, senior staff professionals and third-party contractors and consultants, and the loss of their services could materially adversely affect our business.***

We rely on our relatively small management team and staff as well as various contractors and consultants to provide critical services. Our ability to execute our bremelanotide clinical programs and our preclinical programs on an inhaled formulation of PL-3994 and a new peptide drug candidates for sexual dysfunction and other indications depends on our continued retention and motivation of our management and senior staff professionals, including executive officers and senior members of product development and management who possess significant technical expertise and experience and oversee our development programs. If we lose the services of existing key personnel, our development programs could be adversely affected if suitable replacement personnel are not recruited quickly. Our success also depends on our ability to develop and maintain relationships with contractors, consultants and scientific advisors.

There is competition for qualified personnel, contractors and consultants in the pharmaceutical industry, which makes it difficult to attract and retain the qualified personnel, contractors and consultants necessary for the development and growth of our business.

*Anti-takeover provisions of Delaware law and our charter documents may make potential acquisitions more difficult and could result in the entrenchment of management.*

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with an “interested stockholder” for a period of three years after the date of the transaction in which the person first becomes an “interested stockholder,” unless the business combination is approved in a prescribed manner.

Pursuant to approval by our stockholders at a special meeting of stockholders held on September 27, 2012, we increased our authorized common stock from 100,000,000 to 200,000,000 shares. To the extent that we sell or otherwise issue newly authorized shares, this could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock.

Our charter authorizes us to issue up to 10,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If we exercise this right, it could be more difficult for a third party to acquire a majority of our outstanding voting stock.

In addition, our equity incentive plans generally permit us to accelerate the vesting of options and other stock rights granted under these plans in the event of a change of control. If we accelerate the vesting of options or other stock rights, this action could make an acquisition more costly.

The application of these provisions could have the effect of delaying or preventing a change of control, which could adversely affect the market price of our common stock.

#### **Risks Relating to Obligations in Our 2012 Private Placement**



***Our ability to enter into debt or equity financings is contractually limited for a period under agreements relating to our 2012 private placement of 3,873,000 shares of our common stock and warrants to purchase an aggregate of up to 67,476,531 shares of our common stock.***

Under the purchase agreement and form of warrants for our 2012 private placement which closed on July 3, 2012, we cannot offer, sell or grant any of our equity securities, other than to employees, consultants, officers or directors under an approved stock plan, or enter into any debt placement except in limited circumstances, until September 1, 2013. We do not anticipate needing to raise additional funds prior to September 1, 2013 through the sale of equity securities. However, assuming our drug candidates continue advancing, we will require significant additional resources and capital at some time after September 1, 2013 for our Phase 3 bremelanotide clinical trial program and other clinical trial programs.

***Under agreements relating to our 2012 private placement, we are required to allow purchasers in the 2012 private placement to participate in certain future equity and debt financings, which may restrict our ability to raise funds on acceptable terms, or at all.***

For six years after our 2012 private placement, unless the purchasers own less than 20% of our outstanding common stock calculated as if the warrants were exercised, the purchasers have the right of first negotiation on any subsequent equity or debt financing. If we do not agree to terms of a financing with them, and negotiate with a third party on a financing, we must offer to sell to the purchasers at least 55% of the financing, and the purchasers may elect to purchase all or a portion of the financing. Assuming our drug candidates continue advancing, we will require significant additional resources and capital at some time for our Phase 3 bremelanotide clinical trial program and other clinical trial programs. The right of first negotiation and right of participation granted to the purchasers in our 2012 private placement may make it more difficult to raise additional funding through public or private equity financings, debt financings or other sources. Such funding may not be available on acceptable terms, or at all.

***Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to redeem Series A 2012 and Series B 2012 warrants at the option of the holders in the event of any takeover, change of control or other fundamental transaction which we permit.***

Under the purchase agreement and form of warrants for our 2012 private placement, if we permit, make or allow a takeover, change of control or other fundamental transaction, including any transfer of all or substantially all of our properties or assets, then so long as any warrants remain outstanding we are required, as elected by the warrant holders, to pay such holders a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person. The application of these provisions could adversely affect our financial position and have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition or change of control more costly.



*Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to oppose any takeover or change of control that does not provide specified rights to holders of Series A 2012 and Series B 2012 warrants.*

Under the purchase agreement and form of warrants for our 2012 private placement, so long as any warrants remain outstanding we are required to (i) not permit, (ii) take necessary action to prevent both the occurrence or consummation of, and (iii) not be a party to any fundamental transaction, change of control or similar event unless contractually-specified rights are provided with respect to payment of a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person. We are also required, subject to the exercise by our board of its fiduciary duties, to take all reasonable efforts to adopt a poison pill or any other anti-takeover provision or method necessary to prevent the fundamental transaction, change of control or similar event. The application of these provisions could have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition or change of control more costly.

#### **Risks Relating to Owning Our Common Stock**

*As of November 12, 2012, there were 95,380,815 shares of common stock underlying outstanding convertible preferred stock, options, restricted stock units and warrants. Stockholders may experience dilution from the conversion of preferred stock, exercise of outstanding options and warrants and vesting of restricted stock units.*

As of November 12, 2012, holders of our outstanding dilutive securities had the right to acquire the following amounts of underlying common stock:

- 52,834 shares issuable on the conversion of immediately convertible Series A Convertible preferred stock, subject to adjustment, for no further consideration;
- 2,758,633 shares issuable on the exercise of stock options, at exercise prices ranging from \$0.65 to \$42.10 per share;
- 472,500 shares issuable under restricted stock units which vest on dates between June 22, 2013 and July 17, 2014, subject to the fulfillment of service conditions; and
- 92,096,848 shares issuable on the exercise of warrants at exercise prices ranging from \$0.01 to \$4.12 per share, which includes warrants issued in our 2012 private placement for 67,476,531 shares issuable at an exercise price of \$0.01 per share.

If the holders convert, exercise or receive these securities, or similar dilutive securities we may issue in the future, stockholders may experience dilution in the net tangible book value of their common stock. In addition, the sale or availability for sale of the underlying shares in the marketplace could depress our stock price. We have registered or agreed to register for resale substantially all of the underlying shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, which could result in significant downward pressure on our stock price.

***Our stock price is volatile and we expect it to remain volatile, which could limit investors' ability to sell stock at a profit.***

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

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing preclinical or clinical trials or unsatisfactory designs or results of these trials;
- interim decisions by regulatory agencies, including the FDA, as to clinical trial designs, acceptable safety profiles and the benefit/risk ratio of products under development;
- achievement or rejection of regulatory approvals by our competitors or by us;
- announcements of technological innovations or new commercial products by our competitors or by us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenue and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues, if any, in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer further. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

For the 12 month period ended October 31, 2012, the price of our stock has been volatile, ranging from a high of \$1.20 per share to a low of \$0.39 per share.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

*We do not intend to pay cash dividends in the foreseeable future.*

We do not anticipate paying any cash dividends in the foreseeable future and intend to retain future earnings, if any, for the development and expansion of our business. In addition, the terms of existing or future agreements may limit our ability to pay dividends. Therefore, our stockholders will not receive a return on their shares unless the value of their shares increases.

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

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibits filed or furnished with this report:

- 4.01 Certificate of amendment of restated certificate of incorporation. Incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K, filed with the SEC on September 27, 2012.
- 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.
- 32.2 Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document

**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)

/s/ Carl Spana

Date: November 14, 2012 Carl Spana, Ph.D.  
President and  
Chief Executive Officer (Principal  
Executive Officer)

/s/ Stephen T. Wills

Date: November 14, 2012 Stephen T. Wills, CPA, MST  
Executive Vice President, Chief Financial  
Officer and Chief Operating Officer

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