PALATIN TECHNOLOGIES INC
Form 10-Q
November 14, 2016

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, 2016

or

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

For the transition period from _____ to _____

Commission file number: 001-15543

_____

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

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

| 4B Cedar Brook Drive<br>Cranbury, New Jersey | 08512 |
|---|---|
| (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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

| | |
|---|---|
| Large accelerated filer | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| (Do not check if a smaller reporting company) | |

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

As of November 10, 2016, 108,039,221 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

PALATIN TECHNOLOGIES, INC.
Table of Contents


| | Page |
|---|---|
| PART I – FINANCIAL INFORMATION | |
| Item 1. Financial Statements (Unaudited) | 4 |
| Consolidated Balance Sheets as of September 30, 2016 and June 30, 2016 | 4 |
| Consolidated Statements of Operations for the Three Months Ended September 30, 2016 and 2015 | 5 |
| Consolidated Statements of Comprehensive Loss for the Three Months Ended September 30, 2016 and 2015 | 6 |
| Consolidated Statements of Cash Flows for the Three Months Ended September 30, 2016 and 2015 | 7 |
| Notes to Consolidated Financial Statements | 8 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 17 |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk | 20 |
| Item 4. Controls and Procedures | 20 |
| PART II – OTHER INFORMATION | |
| Item 1. Legal Proceedings | 21 |
| Item 1A. Risk Factors | 21 |
| Item 2. Unregistered Sales of Equity Securities and Use of Proceeds | 23 |
| Item 3. Defaults Upon Senior Securities | 23 |
| Item 4. Mine Safety Disclosures | 23 |
| Item 5. Other Information | 23 |
| Item 6. Exhibits | 23 |
| Signatures | 24 |

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, the following are forward looking statements:

estimates of our expenses, future revenue, capital requirements;

our ability to obtain additional financing on terms acceptable to us, or at all;

our ability to advance product candidates into, and successfully complete, clinical trials;

the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;

the timing or likelihood of regulatory filings and approvals;

our expectations regarding the results and the timing of results in our Phase 3 clinical trials of bremelanotide for the treatment of premenopausal women with hypoactive sexual desire disorder (HSDD), which is a type of female sexual dysfunction, or FSD;

our expectation regarding the timing of our regulatory submissions for approval of bremelanotide for HSDD in the United States and Europe;

the potential for commercialization of bremelanotide for HSDD and other product candidates, if approved, by us;

our expectations regarding the potential market size and market acceptance for bremelanotide for HSDD and our other product candidates, if approved for commercial use;

our ability to compete with other products and technologies similar to our product candidates;

the ability of our third-party collaborators to timely carry out their duties under their agreements with us;

the ability of our contract manufacturers to perform their manufacturing activities for us in compliance with applicable regulations;

our ability to recognize the potential value of our licensing arrangements with third parties;

the potential to achieve revenues from the sale of our product candidates;

our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers;

our ability to maintain product liability insurance at a reasonable cost or in sufficient amounts, if at all;

the retention of key management, employees and third-party contractors;

the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;

our compliance with federal and state laws and regulations;

the timing and costs associated with obtaining regulatory approval for our product candidates;

the impact of fluctuations in foreign exchange rates;

the impact of legislative or regulatory healthcare reforms in the United States;

our ability to adapt to changes in global economic conditions; and

our ability to remain listed on the NYSE MKT.

Such forward-looking statements involve 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, 2016, 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 results may fluctuate significantly from quarter to quarter.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Balance Sheets
(unaudited)

| | September 30, 2016 | June 30, 2016 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $8,867,930 | $8,002,668 |
| Available-for-sale investments | 1,377,714 | 1,380,556 |
| Prepaid expenses and other current assets | 1,007,978 | 1,313,841 |
| Total current assets | 11,253,622 | 10,697,065 |
| Property and equipment, net | 90,171 | 97,801 |
| Other assets | 56,916 | 63,213 |
| Total assets | $11,400,709 | $10,858,079 |
| LIABILITIES AND STOCKHOLDERS' DEFICIENCY | | |
| Current liabilities: | | |
| Accounts payable | $1,159,427 | $713,890 |
| Accrued expenses | 12,884,590 | 7,767,733 |
| Notes payable, net of discount and debt issuance costs | 6,399,075 | 5,374,951 |
| Capital lease obligations | 27,827 | 27,424 |
| Total current liabilities | 20,470,919 | 13,883,998 |
| Notes payable, net of discount and debt issuance costs | 12,162,471 | 14,106,594 |
| Capital lease obligations | 7,214 | 14,324 |
| Other non-current liabilities | 525,314 | 439,130 |
| Total liabilities | 33,165,918 | 28,444,046 |
| Stockholders' deficiency: | | |
| Preferred stock of $0.01 par value – authorized 10,000,000 shares: | | |
| Series A Convertible: issued and outstanding 4,030 shares as of September 30, 2016 and June 30, 2016 | 40 | 40 |
| Common stock of $0.01 par value – authorized 300,000,000 shares: | | |
| issued and outstanding 92,806,710 shares as of September 30, 2016 and 68,568,055 shares as of June 30, 2016, respectively | 928,067 | 685,680 |
| Additional paid-in capital | 333,774,227 | 325,142,509 |
| Accumulated other comprehensive loss | (2,521) | (1,944) |

| | | |
|---|---|---|
| Accumulated deficit | (356,465,022) | (343,412,252) |
| Total stockholders' deficiency | (21,765,209) | (17,585,967) |
| Total liabilities and stockholders' deficiency | $11,400,709 | $10,858,079 |

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 September 30, | |
|---|---|---|
| | 2016 | 2015 |
| REVENUES: | | |
| License revenue | $- | $- |
| OPERATING EXPENSES: | | |
| Research and development | 11,226,084 | 10,597,714 |
| General and administrative | 1,209,346 | 1,199,937 |
| Total operating expenses | 12,435,430 | 11,797,651 |
| Loss from operations | (12,435,430) | (11,797,651) |
| OTHER INCOME (EXPENSE): | | |
| Interest income | 6,645 | 15,740 |
| Interest expense | (623,985) | (628,008) |
| Total other income (expense), net | (617,340) | (612,268) |
| NET LOSS | $(13,052,770) | $(12,409,919) |
| Basic and diluted net loss per common share | $(0.08) | $(0.08) |
| Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share | 165,848,269 | 156,176,618 |

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

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Comprehensive Loss
(unaudited)

| | Three Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| Net loss | $(13,052,770) | $(12,409,919) |
| Other comprehensive loss: | | |
| Unrealized loss on available-for-sale investments | (577) | - |
| Total comprehensive loss | $(13,053,347) | $(12,409,919) |

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 September 30, | |
|---|---|---|
| | 2016 | 2015 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $(13,052,770) | $(12,409,919) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 7,630 | 10,654 |
| Non-cash interest expense | 82,266 | 80,739 |
| Stock-based compensation | 403,208 | 300,394 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 312,160 | 137,095 |
| Accounts payable | 445,537 | 2,239,604 |
| Accrued expenses | 5,116,857 | 156,062 |
| Other non-current liabilities | 86,184 | 86,957 |
| Net cash used in operating activities | (6,598,928) | (9,398,414) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of property and equipment | - | (17,695) |
| Net cash used in investing activities | - | (17,695) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Payments on capital lease obligations | (6,707) | (6,328) |
| Payment of withholding taxes reltaed to restricted stock units | - | (131,959) |
| Payment on notes payable obligations | (1,000,000) | - |
| Proceeds from the sale of common stock and warrants, net of costs | 8,470,897 | 19,919,883 |
| Proceeds from the issuance of notes payable and warrants | - | 10,000,000 |
| Payment of debt issuance costs | - | (140,964) |
| Net cash provided by financing activities | 7,464,190 | 29,640,632 |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 865,262 | 20,224,523 |
| CASH AND CASH EQUIVALENTS, beginning of period | 8,002,668 | 27,299,268 |

| | | |
|---|---|---|
| CASH AND CASH EQUIVALENTS, end of period | $8,867,930 | $47,523,791 |
| | | |
| SUPPLEMENTAL CASH FLOW INFORMATION: | | |
| Cash paid for interest | $457,800 | $460,313 |
| Issuance of warrants in connection with debt financing | - | 305,196 |
| Unrealized loss on available-for-sale investments | 577 | - |
| Non-cash equity financing costs in accounts payable | 21,029 | 85,605 |
| Non-cash equity financing costs in accrued expenses | 65,000 | - |
| Non-cash debt financing costs in accounts payable | - | 5,151 |

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, cachexia (wasting syndrome) 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 hypoactive sexual desire disorder (HSDD), which is a type of female sexual dysfunction (FSD). The Company also has drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

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 third parties.

Going Concern – There is substantial doubt about the Company's ability to continue as a going concern. Since inception, the Company has incurred negative cash flows from operations, and has expended, and expects to continue to expend, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company had an accumulated deficit as of September 30, 2016 of $356,465,022 and incurred a net loss for the three months ended September 30, 2016 of $13,052,770. The Company anticipates incurring additional losses in the future as a result of spending on its development programs and will require substantial additional financing to continue to fund its planned developmental activities. To achieve profitability, if ever, 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 the Company may never be able to achieve profitability on a sustained basis, if at all. The accompanying consolidated financial statements have been prepared assuming that the Company continues as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amount or classification of liabilities that might result from the outcome of this uncertainty.

As discussed in Note 11, on August 4, 2016, the Company closed on an underwritten offering of units resulting in gross proceeds of $9,225,000, with net proceeds, after deducting estimated offering expenses, of $8,470,897.

As of September 30, 2016, the Company's cash, cash equivalents and investments were $10,245,644 and current liabilities were $20,470,919. The Company intends to utilize existing capital resources for general corporate purposes and working capital, including the Phase 3 clinical trial program with bremelanotide for HSDD and preclinical and clinical development of our other product candidates and programs, including PL−3994 and melanocortin receptor−1 and melanocortin receptor−4 programs. Management believes that the Phase 3 clinical trial program with bremelanotide for HSDD, including regulatory filings for product approval, but excluding required ancillary studies

and clinical trials and launch readiness commercialization efforts, will cost at least $87,000,000.

Management believes that the Company's existing capital resources will be adequate to fund its planned operations through the quarter ending December 31, 2016. The Company will need additional funding to complete required ancillary studies and clinical trials of bremelanotide for HSDD, prepare and submit regulatory filings for product approval, and establish commercial scale manufacturing capability. The Company will also need additional funding to complete required clinical trials for its other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required applications to the FDA. If the Company is unable to obtain approval or otherwise advance in the FDA approval process, the Company's ability to sustain its operations would be materially adversely affected.

The Company may seek the additional capital necessary to fund its operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. Additional capital that is required by the Company may not be available on reasonable terms, or at all.

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 and available−for−sale investments. The Company's cash and cash equivalents are primarily invested in one money market account sponsored by a large financial institution. For the three months ended September 30, 2016, and 2015, the Company had no revenues reported.

(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 for fair presentation. The results of operations for the three months ended September 30, 2016 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, 2017.

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, 2016, filed with the Securities and Exchange Commission (SEC), which includes consolidated financial statements as of June 30, 2016 and 2015 and for each of the fiscal years in the three-year period ended June 30, 2016.

(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 intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates – The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) 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 $8,687,904 and $7,782,243 in a money market account at September 30, 2016 and June 30, 2016, respectively.

Investments – The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such determinations at each balance sheet date. Debt securities are classified as held−to−maturity when the Company has the intent and ability to hold the securities to maturity. Debt securities for which the Company does not have the intent or ability to hold to maturity are classified as available−for−sale. Held−to−maturity securities are recorded as either short−term or long−term on the balance sheet, based on the contractual maturity date and are stated at amortized cost. Marketable securities that are bought and held principally for the purpose of selling them in the near term are classified as trading securities and are reported at fair value, with unrealized gains and losses recognized in earnings. Debt and marketable equity securities not classified as held−to−maturity or as trading are classified as available−for−sale and are carried at fair market value, with the unrealized gains and losses, net of tax, included in the determination of other comprehensive (loss) income.

The fair value of substantially all securities is determined by quoted market prices. The estimated fair value of securities for which there are no quoted market prices is based on similar types of securities that are traded in the market.

Fair Value of Financial Instruments – The Company's financial instruments consist primarily of cash equivalents, available-for-sale investments, accounts payable and notes payable. Management believes that the carrying values of cash equivalents, available-for-sale investments and accounts payable are representative of their respective fair values based on the short-term nature of these instruments. Management believes that the carrying amount of its notes payable approximates fair value based on the terms of the notes.

Credit Risk – Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. Total cash and cash equivalent balances have exceeded insured balances by the Federal Depository Insurance Company (FDIC).

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.

Revenue Recognition – Under our license, co-development and commercialization agreement with Gedeon Richter (Note 5), we received consideration in the form of a license fee and development milestone payment.

Revenue resulting from license fees is recognized upon delivery of the license for the portion of the license fee payment that is non-contingent and non-refundable, if the license has standalone value. Revenue resulting from the achievement of development milestones is recorded in accordance with the accounting guidance for the milestone method of revenue recognition.

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.

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

Stock-Based Compensation – The 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 determined using the quoted market price of the Company's common stock on the date of grant and allocated to periods on a straight–line basis, while awards containing a market condition are valued using multifactor Monte Carlo simulations.

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," which includes guidance pertaining to the warrants, issued in connection with the July 3, 2012, December 23, 2014, and July 2, 2015 private placement offerings and the August 4, 2016 underwritten offering, that 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 issued on July 3, 2012 to purchase up to 31,988,151 shares of common stock are included in the weighted average number of common shares outstanding used in computing basic and diluted net loss per common share for all periods presented in the consolidated statements of operations.

The Series B 2012 warrants issued on July 3, 2012 to purchase up to 35,488,380 shares of common stock are included in the weighted average number of common shares outstanding used in computing basic and diluted net loss per common share for all periods presented in the consolidated statements of operations.

The Series C 2014 warrants to purchase up to 24,949,325 shares of common stock were exercisable starting at December 23, 2014 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 December 23, 2014.

10

The Series E 2015 warrants to purchase up to 21,917,808 shares of common stock were exercisable starting at July 2, 2015 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 2, 2015.

The Series I 2016 warrants to purchase up to 2,218,045 shares of common stock were exercisable starting at August 4, 2016 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 August 4, 2016 (Note 11).

As of September 30, 2016 and 2015, common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding options and warrants (excluding the Series A 2012, Series B 2012, Series C 2014, Series E 2015 and Series I 2016 warrants issued in connection with the July 3, 2012, December 23, 2014, and July 2, 2015 private placement offerings and the August 4, 2016 underwritten offering), and the vesting of restricted stock units amounted to an aggregate of 44,479,663, and 32,908,798 shares, respectively. These share amounts have been excluded from the calculation of net loss per share as the impact would be anti−dilutive.

(4)

NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS:

In June 2016, the FASB issued ASU No. 2016−13, Financial Instruments − Credit Losses: Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the current guidance as this will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets. The new guidance will be effective for the Company on July 1, 2020. Early adoption will be available on July 1, 2019. The Company is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016−09, Compensation – Improvement to Employee Share−Based Payment Accounting, which amends the current guidance related to stock compensation. The updated guidance changes how companies account for certain aspects of share−based payment awards to employees, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The update to the standard is effective for the Company on July 1, 2017, with early application permitted. The Company is evaluating the effect that the new guidance will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016−02, Leases, Related to the Recognition of Lease Assets and Lease Liabilities. The new guidance requires lessees to recognize almost all leases on their balance sheet as a right−of−use asset and a lease liability, other than leases that meet the definition of a short− term lease, and requires expanded disclosures about leasing arrangements. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from the current guidance. Lessor accounting is similar to the current guidance, but updated to align with certain changes to the lessee model and the new revenue recognition standard. The new guidance is effective for the Company on July 1, 2019, with early adoption permitted. The Company is evaluating the impact that the new guidance will have on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016−01, Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance relates to the recognition and measurement of financial assets and liabilities. The new guidance makes targeted improvements to GAAP impacting equity investments (other than those accounted for under the equity method or consolidated), financial liabilities accounted for under the fair value election, and presentation and disclosure requirements for financial instruments, among other changes. The new guidance is effective for the Company on July 1, 2018, with early adoption prohibited other than for certain provisions. The Company is evaluating the impact that the new guidance will have on its consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015−17, Income Taxes: Balance Sheet Classification of Deferred Taxes, which simplifies the balance sheet classification of deferred taxes. The new guidance requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax−paying component of an entity be offset and presented as a single

amount is not affected by the new guidance. The new guidance is effective for the Company on July 1, 2017, with early adoption permitted as of the beginning of an interim or annual reporting period. The new guidance may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company is evaluating the impact that the new guidance will have on its consolidated financial statements and related disclosures. however, at the present time the Company has recorded a valuation allowance against its deferred tax assets based on the history of losses incurred.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs, which requires debt issuance costs related to a recognized debt liability to be presented on the balance sheet as a direct deduction from the debt liability, similar to the presentation of debt discounts. In August 2015, the FASB issued a clarification that debt issuance costs related to line-of-credit arrangements were not within the scope of the new guidance and therefore should continue to be accounted for as deferred assets in the balance sheet, consistent with existing GAAP. The Company adopted the retrospective guidance as of July 1, 2016. As a result of the adoption of ASU No. 2015-03, we made the following adjustments to the June 30, 2016 consolidated balance sheet: a $110,441 decrease to prepaid expenses and other current assets, a $83,215 decrease to other assets, a $110,441 decrease to the current portion of notes payable, net of discounts and debt issuance costs, and a $83,215 decrease to the long-term portion of notes payable, net of discounts and debt issuance costs.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements-Going Concern: Disclosures of Uncertainties about an Entity’s Ability to Continue as a Going Concern. The amendments in this update provide guidance in U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The new standard is effective for the Company for its fiscal year ending June 30, 2017. The Company is evaluating the effect of the standard, if any, on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. With the deferral, the new standard is effective for the Company on July 1, 2018, with early adoption permitted one year prior. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

(5)

AGREEMENT WITH GEDEON RICHTER:

In August 2014, the Company entered into a license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for FSD in Europe and selected countries. On September 16, 2015, the Company and Gedeon Richter mutually and amicably agreed to terminate the license, co-development and commercialization agreement. In connection with the termination of the license agreement, all rights and licenses to co-develop and commercialize bremelanotide for FSD indications granted by the Company under the license agreement to Gedeon Richter terminated and reverted to the Company, and neither party is expected to have any future material obligations under the license agreement. Neither the Company nor Gedeon Richter incurred any early termination penalties or other payment or reimbursement obligations as a result of the termination of the license agreement.

The Company viewed the delivery of the license for bremelanotide as a revenue generating activity that is part of its ongoing and central operations. The other elements of the agreement with Gedeon Richter were considered non-revenue activities associated with the collaborative arrangement. The Company believes the license had standalone value from the other elements of the collaborative arrangement because it conveyed all of the rights necessary to develop and commercialize bremelanotide in the licensed territory. For the three months ended September 30, 2016, and 2015, the Company had no revenues reported.

(6)

PREPAID EXPENSES AND OTHER CURRENT ASSETS:

Prepaid expenses and other current assets consist of the following:

| | September 30, 2016 | June 30, 2016 |
|---|---|---|

| | | |
|---|---|---|
| Clinical study costs | $860,440 | $1,146,975 |
| Insurance premiums | 25,764 | 23,010 |
| Other | 121,774 | 143,856 |
| | $1,007,978 | $1,313,841 |

(7)
INVESTMENTS:
The following summarizes the carrying value of our available−for−sale investments, which consist of corporate debt securities:

| | September 30, 2016 | June 30, 2016 |
|---|---|---|
| Cost | $1,387,022 | $1,387,022 |
| Amortization of premium | (6,787) | (4,522) |
| Gross unrealized loss | (2,521) | (1,944) |
| Fair value | $1,377,714 | $1,380,556 |

(8)
FAIR VALUE MEASUREMENTS:
The fair value of cash equivalents is 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:

| | Carrying Value | Quoted prices in active markets (Level 1) | Other quoted/observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
|---|---|---|---|---|
| September 30, 2016: | | | | |
| Money market account | 8,687,904 | 8,687,904 | - | - |
| TOTAL | $8,687,904 | $8,687,904 | $- | $- |
| June 30, 2016: | | | | |
| Money market account | 7,782,243 | 7,782,243 | - | - |
| TOTAL | $7,782,243 | $7,782,243 | $- | $- |

(9)
ACCRUED EXPENSES:
Accrued expenses consist of the following:

| | September 30, 2016 | June 30, 2016 |
|---|---|---|
| Bremelanotide program costs | $12,379,580 | $6,983,581 |
| Other research related expenses | 311,178 | 69,609 |
| Professional services | 40,235 | 231,482 |
| Other | 153,597 | 483,061 |
| | $12,884,590 | $7,767,733 |

(10)
NOTES PAYABLE:
Notes payable consist of the following:

| | September 30, 2016 | June 30, 2016 |
|---|---|---|
| Notes payable under venture loan | $19,000,000 | $20,000,000 |
| Unamortized related debt discount | $(275,386) | $(324,800) |
| Unamortized debt issuance costs | (163,068) | (193,655) |

| | | |
|---|---|---|
| Notes payable | $18,561,546 | $19,481,545 |
| Less: current portion | 6,399,075 | 5,374,951 |
| Long-term portion | $12,162,471 | $14,106,594 |

On July 2, 2015, the Company closed on a $10,000,000 venture loan led by Horizon Technology Finance Corporation (Horizon). The debt facility is a four-year senior secured term loan that bears interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50% and provides for interest-only payments for the first eighteen months followed by monthly payments of principal payments of $333,333 plus accrued interest through August 1, 2019. The lenders also received five-year immediately exercisable Series G warrants to purchase 549,450 shares of Palatin common stock exercisable at an exercise price of $0.91 per share. The Company has recorded a debt discount of $305,196 equal to the fair value of these warrants at issuance, which is being amortized to interest expense over the term of the related debt. This debt discount will offset against the note payable balance and is included in additional paid-in capital on the Company's balance sheet at September 30, 2016 and June 30, 2016. In addition, a final incremental payment of $500,000 is due on August 1, 2019, or upon early repayment of the loan. This final incremental payment is being accreted to interest expense over the term of the related debt. The Company incurred approximately $146,000 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and are offset against the note payable balance. These debt issuance costs are being amortized to interest expense over the term of the related debt. In addition, if the Company repays all or a portion of the loan prior to the applicable maturity date, it will pay the lenders a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs on or before 18 months after the funding date thereof or 1% if the prepayment occurs more than 18 months after, but on or before 30 months after, the funding date.
On December 23, 2014, the Company closed on a $10,000,000 venture loan which was led by Horizon. The debt facility is a four year senior secured term loan that bears interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50%, and provides for interest-only payments for the first eighteen months followed by monthly payments of principal payments of $333,333 plus accrued interest through January 1, 2019. The lenders also received five-year immediately exercisable Series D 2014 warrants to purchase 666,666 shares of common stock exercisable at an exercise price of $0.75 per share. The Company recorded a debt discount of $267,820 equal to the fair value of these warrants at issuance, which is being amortized to interest expense over the term of the related debt. This debt discount is offset against the note payable balance and included in additional paid-in capital on the Company's balance sheet at September 30, 2016, and June 30, 2016. In addition, a final incremental payment of $500,000 is due on January 1, 2019, or upon early repayment of the loan. This final incremental payment is being accreted to interest expense over the term of the related debt. The Company incurred $209,000 of costs in connection with the loan agreement These costs were capitalized as deferred financing costs and are offset against the note payable balance. These debt issuance costs are being amortized to interest expense over the term of the related debt. In addition, if the Company repays all or a portion of the loan prior to the applicable maturity date, it will pay the lenders a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs on or before 18 months after the funding date thereof or 1% if the prepayment occurs more than 18 months after, but on or before 30 months after, the funding date.
The Company's obligations under the 2015 amended and restated loan agreement, which includes the 2014 venture loan, are secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company also has agreed to specified limitations on pledging or otherwise encumbering its intellectual property assets.
The 2015 amended and restated loan agreement include customary affirmative and restrictive covenants, but does not include any covenants to attain or maintain specified financial metrics. The loan agreement includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan agreement. As of September 30, 2016, the Company was in compliance with all of its loan covenants.
(11)
STOCKHOLDERS' DEFICIENCY:
Financing Transactions – On August 4, 2016, the Company closed on an underwritten offering of units, with each unit consisting of a share of common stock and a Series H warrant to purchase 0.75 of a share of common stock. Investors

whose purchase of units in the offering would result in them beneficially owning more than 9.99% of the Company's outstanding common stock following the completion of the offering had the opportunity to acquire units with Series I prefunded warrants substituted for any common stock they would have otherwise acquired. Gross proceeds were $9,225,000, with net proceeds to the Company, after deducting offering expenses, of $8,470,897. The Company issued 11,481,481 shares of common stock and ten year prefunded Series I warrants to purchase 2,218,045 shares of common stock at an exercise price of $0.01, together with Series H warrants to purchase 10,274,646 shares of common stock at an exercise price of $0.70 per share.

The Series I warrants are exercisable at an initial exercise price of $0.01 per share, exercisable immediately upon issuance and expire on the tenth anniversary of the date of issuance. The Series I warrants are subject to limitation on exercise if the holder and its affiliates would beneficially own more than 9.99% of the total number of the Company's shares of common stock following such exercise. The Series H warrants are exercisable at an initial exercise price of $0.70 per share, are exercisable commencing six months following the date of issuance and expire on the fifth anniversary of the date of issuance. The Series H warrants are subject to the same beneficial ownership limitation as the Series I warrants.

On July 2, 2015, the Company closed on a private placement of Series E warrants to purchase 21,917,808 shares of Palatin common stock and Series F warrants to purchase 2,191,781 shares of the Company's common stock. Certain funds managed by QVT Financial LP (QVT) invested $5,000,000 and another accredited investment fund invested $15,000,000. The funds paid $0.90 for each Series E warrant and $0.125 for each Series F warrant, resulting in gross proceeds to the Company of $20,000,000, with net proceeds, after deducting estimated offering expenses, of $19,834,278.

The Series E warrants, which may be exercised on a cashless basis, are exercisable immediately upon issuance at an initial exercise price of $0.01 per share and expire on the tenth anniversary of the date of issuance. The Series E warrants are subject to limitation on exercise if QVT and its affiliates would beneficially own more than 9.99% (4.99% for the other accredited investment fund holder) of the total number of the Company's shares of common stock following such exercise. The Series F warrants are exercisable at an initial exercise price of $0.91 per share, exercisable immediately upon issuance and expire on the fifth anniversary of the date of issuance. The Series F warrants are subject to the same beneficial ownership limitation as the Series E warrants.

The purchase agreement for the private placement provides that the purchasers have certain rights until the earlier of approval of bremelanotide for FSD by the U.S. Food and Drug Administration and July 3, 2018, including rights of first refusal and participation in any subsequent equity or debt financing. 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.

During the three months ended September 30, 2016, and 2015 the Company issued 12,757,174 shares and 10,890,889 shares, respectively, of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of $0.01 per share. As of September 30, 2016, there were 77,546,764 warrants outstanding at an exercise price of $0.01 per share.

Stock Options – In September 2016, the Company granted 828,000 options to its executive officers and 336,000 options to its employees under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of the options vesting over a 48 month period, consisting of 595,000 options granted to its executive officers and all options granted to its employees, of $188,245 and $106,303, respectively, over the vesting period. The Company recognized $5,216 of stock-based compensation expense related to these options during the three months ended September 30, 2016. 233,000 options granted to its executive officers vest 12 months from the date of grant, and the Company is amortizing the fair value of these options of $67,160 over this vesting period. The Company recognized $4,757 of stock-based compensation expense related to these options during the three months ended September 30, 2016.

In June 2016, the Company granted 262,500 options to its non−employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $81,435 over the vesting period. The Company recognized $20,359 of stock-based compensation expense related to these options during the three months ended September 30, 2016.

In June 2015, the Company granted 570,000 options to its executive officers, 185,800 options to its employees and 160,000 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $446,748, $145,439 and $111,876, respectively, over the vesting period. The Company recognized $32,293, and $57,577, respectively, of stock-based compensation expense related to these options during the three months ended September 30, 2016 and 2015.

Unless otherwise stated, stock options granted to the Company's executive officers and employees vest over a 48 month period, while stock options granted to its non-employee directors vest over a 12 month period.

Restricted Stock Units – In September 2016, the Company granted 558,000 restricted stock units to its executive officers, 415,000 of which vest over 24 months and 143,000 of which vest at 12 months, and 336,000 restricted stock units to its employees under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of the restricted stock units of $284,580, and $171,360, respectively, over the vesting periods. The Company recognized $20,504 of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2016.

In June 2016, the Company granted 262,500 restricted stock units to its non−employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of $131,250 over

the vesting period. The Company recognized $32,812 of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2016.

In December 2015, the Company granted 625,000 performance-based restricted stock units to its executive officers and 200,000 performance-based restricted stock units to its employees under the Company's 2011 Stock Incentive Plan, which vest during the performance period, ending December 31, 2017, if and upon the earlier of: i) achievement of a closing price for the Company's common stock equal to or greater than $1.20 per share for 20 consecutive trading days, which is considered a market condition, or ii) entering into a collaboration agreement (U.S. or global) of bremelanotide for FSD, which is considered a performance condition. The Company determined that the performance condition was not probable of achievement on the date of grant since such condition is outside the control of the Company. The fair value of these awards, as calculated under a multifactor Monte Carlo simulation, was $338,250. The Company is amortizing the fair value over the derived service period of 0.96 years. The Company recognized $86,879 of stock-based compensation expense related to these restricted stock units during the three ended September 30, 2016.

Also, in December 2015, the Company granted 625,000 restricted stock units to its executive officers, 340,000 restricted stock units to its non-employee directors and 200,000 restricted stock units to its employees under the Company's 2011 Stock Incentive Plan. For executive officers and employees, the restricted stock units vest 25% on the date of grant and 25% on the first, second and third anniversary dates from the date of grant. For non-employee directors, the restricted stock units vest 50% on the first and second anniversary dates from the date of grant. The fair value of these restricted stock units is $425,000, $231,200 and $136,000, respectively. The Company recognized $101,256 of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2016.

In June 2015, the Company granted 400,000 restricted stock units to its executive officers, 185,800 restricted stock units to its employees and 160,000 restricted stock units to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of $432,000, $200,664, and $172,800, respectively, over the vesting period. The Company recognized $40,429 and $150,328, respectively, of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2016 and 2015.

Unless otherwise stated, restricted stock units granted to the Company's executive officers, employees and non-employee directors vest over 24 months, 48 months and 12 months, respectively.

Stock-based compensation cost for the three months ended September 30, 2016 for stock options and equity-based instruments issued other than the stock options and restricted stock units described above was $58,703, and $92,489 for the three months ended September 30, 2015.

(12)

SUBSEQUENT EVENTS:

Bremelanotide Phase 3 HSDD Topline Results – On November 1, 2016, we announced positive top-line results in our Phase 3 clinical trial program of bremelanotide as an on-demand treatment for premenopausal women diagnosed with HSDD. Bremelanotide 1.75 mg met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments.

Outstanding Common Stock – Between September 30, 2016 and November 10, 2016, the Company issued 15,232,511 shares of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of $0.01 per share. As of November 10, 2016, there are 62,046,764 outstanding warrants with an exercise price of $0.01 per share, all of which include cashless exercise provisions.

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, 2016.

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, which 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, 2016, have not changed as of September 30, 2016. 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 premenopausal women with hypoactive sexual desire disorder, or HSDD, which is a type of female sexual dysfunction, or FSD, defined as low desire with associated distress. In addition, we have drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

The following drug development programs are actively under development:

Bremelanotide, an-as needed subcutaneous injectable peptide melanocortin receptor agonist, for treatment of HSDD in premenopausal women. Bremelanotide, which is a melanocortin agonist, is a synthetic peptide analog of the naturally occurring hormone alpha−MSH (melanocyte−stimulating hormone). In two primary Phase 3 clinical studies of bremelanotide for HSDD in premenopausal women, bremelanotide met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments.

Melanocortin receptor−4, or MC4r, compounds for treatment of obesity and diabetes. Results of our studies involving MC4r peptides suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, HSDD, erectile dysfunction or ED, obesity and diabetes.

PL−3994, a natriuretic peptide receptor−A, or NPR−A, agonist, for treatment of cardiovascular and pulmonary indications. PL−3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone atrial natriuretic peptide, or ANP. PL−3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension. and

Melanocortin receptor−1, or MC1r, agonist peptides for treatment of inflammatory and dermatologic disease indications. Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. We have selected one of our MC1r peptide drug candidates, designated PL−8177, as a clinical trial candidate.

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

We are developing subcutaneously administered bremelanotide for the treatment of HSDD in premenopausal women. HSDD is characterized by a decrease in sexual desire with significant personal distress or interpersonal difficulty as a result of the lack of desire. Bremelanotide is a melanocortin agonist with a mechanism of action involving activation of endogenous neuronal pathways regulating sexual arousal and desire responses.

We initiated patient screening in our Phase 3 clinical study program of bremelanotide for the treatment of HSDD in premenopausal women, called the RECONNECT STUDY, in the fourth quarter of calendar 2014, completed patient enrollment in the fourth quarter of calendar 2015, and completed the last patient visits in the double blind, or efficacy, portion of the studies in the third quarter of calendar 2016. There are two Phase 3 clinical trials, Study 301 and Study 302, in the RECONNECT STUDY. The co-primary endpoints for the Phase 3 clinical trials were the Female Sexual Function Index: Desire Domain (FSFI-D) and Female Sexual Distress Scale-Desires/Arousal/Orgasm (FSDS-DAO) Item 13. For women taking bremelanotide compared to placebo, the FSFI-D showed statistically significant improvement in measures of desire in the context of overall sexual functioning in both Phase 3 studies, Study 301: (mean change of 0.54 vs. 0.24, median change of 0.60 vs. 0.00, p=0.0002) and Study 302: (mean change of 0.63 vs. 0.21, median change of 0.60 vs. 0.00, p<0.0001). The FSDS-DAO Item 13 showed statistically significant decreases in measures of distress related to low sexual desire both Phase 3 studies, Study 301: (mean change of -0.74 vs. -0.35, median change of -1.0 vs. 0.0, p<0.0001) and Study 302: (mean change of -0.71 vs. -0.41, median change of -1.0 vs. 0.0, p=0.0057). The open−label safety extension portion of the RECONNECT STUDY is continuing. We cannot assure you that a complete review of the Phase 3 efficacy data will support approval of bremelanotide for HSDD or that the U.S. Food and Drug Administration, or FDA, will approve a new drug application, or NDA, for bremelanotide.

Key elements of our business strategy include:

Using our technology and expertise to develop and commercialize products in our active drug development programs;

Entering into strategic alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing;

Partially funding our product development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties; and

Completing development and seeking regulatory approval of bremelanotide for HSDD and our other product candidates.

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, 2016 Compared to the Three Months Ended September 30, 2015

Revenue – We recognized no revenue for the three months ended September 30, 2016 and 2015.

Research and Development – Research and development expenses were $11,226,084 for the three months ended September 30, 2016 compared to $10,597,714 for the three months ended September 30, 2015.

Research and development expenses related to our bremelanotide, PL-3994, MC1r, MC4r and other preclinical programs were $10,098,974 for the three months ended September 30, 2016 compared to $9,887,540 for the three months ended September 30, 2015. Spending to date has been primarily related to our bremelanotide for the treatment of HSDD program. The increase in research and development expenses is mainly attributable to the continued progress of our bremelanotide program for HSDD. 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 were $1,127,110 for the three months ended September 30, 2016 compared to $710,174 for the three months ended September 30, 2015. The increase in general research and development spending is primarily attributable to additional staffing and secondarily to the recognition of stock−based compensation.

Cumulative spending from inception to September 30, 2016 is approximately $245,600,000 on our bremelanotide program and approximately $124,300,000 on all our other programs (which include PL−3994, PL−8177, other melanocortin receptor agonists, obesity, other discovery programs and terminated programs). Due to various risk factors described herein and in our Annual Report on Form 10-K for the year ended June 30, 2016, under “Risk Factors,” including the difficulty in 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, be successfully completed, or generate net cash inflows.

General and Administrative – General and administrative expenses, which consist mainly of compensation and related costs, were $1,209,346 for the three months ended September 30, 2016 compared to $1,199,937 for the three months ended September 30, 2015. The increase in general and administrative expenses is primarily attributable to the recognition of stock−based compensation.

Other Income (Expense) – Other income (expense) was $(617,340), and $(612,268), respectively, for the three months ended September 30, 2016 and 2015. For the three months ended September 30, 2016, we recognized $6,645 of investment income offset by $(623,985) of interest expense primarily related to our venture debt. For the three months ended September 30, 2015, we recognized $15,740 of investment income offset by $(628,008) of interest expense primarily related to our venture debt.

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 debt and 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 (GMP) compliance;

intellectual property rights;

product introduction;

marketing, sales and competition; and

obtaining sufficient capital.

Failure to enter into or successfully perform under 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, 2016, cash used for operating activities was $6,598,928, compared to $9,398,414 for the three months ended September 30, 2015. Lower net cash outflows from operations in the three months ended September 30, 2016 compared to the three months ended September 30, 2015 were primarily the result of an increase in accrued expenses and an increase in accounts payable. Our periodic prepaid expenses, accounts payable and accrued expenses balances will continue to be highly dependent on the timing of our operating costs.
During the three months ended September 30, 2016 there were no investing activities. During the three months ended September 30, 2015, net cash used for investing activities was $17,695 for capital expenditures.
During the three months ended September 30, 2016, net cash provided by financing activities was $7,464,190, which consisted of an underwritten offering with net proceeds of $8,470,897, offset by $1,006,707 for the payment on notes payable and capital lease payments. During the three months ended September 30, 2015, net cash provided by financing activities of $29,640,632 consisted of net proceeds of $19,919,883 from a private placement, a loan of $9,859,036, net of related debt issuance costs, offset by approximately $138,287 for the payment of withholding taxes related to restricted stock units and capital lease payments.
We have incurred cumulative negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. As a result, there is substantial doubt about our ability to continue as a going concern. Continued operations are dependent upon our ability to complete equity or debt financing activities or collaboration arrangements. We believe that if we do not have sufficient funding, we may have to curtail or cease certain programs or operations within twelve months. As of September 30, 2016, our cash, cash equivalents and investments were $10,245,644 and our current liabilities were $20,470,919.
We intend to utilize existing capital resources for general corporate purposes and working capital, including our bremelanotide program for HSDD, preclinical and clinical development of our MC1r and MC4r peptide programs and PL−3994 natriuretic peptide, and development of other portfolio products. Based on our current plan, we believe that the Phase 3 clinical trial program with bremelanotide for HSDD, including regulatory filings for product approval, but excluding required ancillary studies and clinical trials and launch readiness commercialization efforts, will cost at least $87,000,000. We intend to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide, public or private equity or debt financings, or other sources.
We believe that our existing capital resources will be adequate to fund our planned operations through the quarter ending December 31, 2016. To submit an NDA to FDA for bremelanotide for HSDD, we will need additional funding to complete required ancillary studies and clinical trials, prepare and submit regulatory filings for product approval, and establish commercial scale manufacturing capability. We will also need additional funding to complete required clinical trials for our other product candidates and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA.
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, 2016.
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.

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance, and they involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties facing our business. We have described in our Annual Report on Form 10-K for the fiscal year ended June 30, 2016, the primary risks related to our business, and we periodically update those risks for material developments. Those risks are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions and geopolitical events. Further, additional risks that materially and adversely affect our business, operations, liquidity and stock price may materialize in the future.

Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended June 30, 2016, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

We will need additional financing, including financing to submit required regulatory applications to the FDA for bremelanotide for HSDD and to complete clinical trials for our other product candidates, which may not be available on acceptable terms, if at all.

As of September 30, 2016, we had cash, cash equivalents and investments of $10,245,644, with current liabilities of $20,470,919. We believe we currently have sufficient existing capital resources to fund our planned operations through the quarter ending December 31, 2016. We will need additional funding to complete development of our bremelanotide for HSDD program, including completing ancillary studies and clinical trials, completing certain chemistry, manufacturing and controls activities, preparing and submitting regulatory filings for product approval, and launch readiness commercialization efforts. We will also need additional funding to conduct and complete required clinical trials for our other product candidates and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA.

We have completed the last patient visits in the double blind portion of our Phase 3 clinical trial of bremelanotide for HSDD, and subsequent to the end of the quarter we released top-line results. We believe we have adequate funds to complete analysis of efficacy and safety data. However, we do not have adequate funds to complete the open-label safety extension study, all ancillary studies and clinical trials required for submission of an NDA to FDA for approval of bremelanotide for HSDD, or to prepare and submit the NDA to FDA. We may be required to curtail or delay our bremelanotide for HSDD program unless we have adequate funds to complete the program. We estimate that the Phase 3 clinical trial program with bremelanotide for HSDD, including regulatory filings for product approval, but excluding required ancillary studies and clinical trials and launch readiness commercialization efforts, will cost at least $87,000,000, of which approximately $63,800,000 has been expensed through September 30, 2016. We will seek funds to support the program through collaborative arrangements on bremelanotide, including marketing and distribution partnering agreements, public or private equity or debt financings, and other sources, but such additional funding may not be available on acceptable terms, or at all.

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 or debt financings, collaborative arrangements on our product candidates, or other sources. However, such financing arrangements 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 decrease staffing levels. We may seek to license, sell or otherwise dispose of our product candidates, technologies and contractual rights 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.

Our future capital requirements depend on many factors, including:

the interpretation and acceptance of the results of our Phase 3 clinical trials for bremelanotide for HSDD;

the complete results of our Phase 3 clinical trials for bremelanotide for HSDD;

the timing of, and the costs involved in, obtaining regulatory approvals for bremelanotide for HSDD and our other product candidates;

the number and characteristics of any additional product candidates we develop or acquire;

the scope, progress, results and costs of researching and developing bremelanotide for HSDD, PL-3994 or any future product candidates, and conducting preclinical and clinical trials;

the cost of commercialization activities if bremelanotide for HSDD, PL-3994 or any future product candidates are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing bremelanotide for HSDD, PL-3994 or any future product candidates and any products we successfully commercialize;

our ability to establish and maintain strategic collaborations, licensing or other arrangements and the terms and timing of such arrangements;

the degree and rate of market acceptance of any future approved products;

the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;

any product liability or other lawsuits related to our products;

the expenses needed to attract and retain skilled personnel;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate, bremelanotide for HSDD, but we may never obtain regulatory approval for or successfully commercialize bremelanotide for HSDD or any of our product candidates.

To date, we have invested most of our efforts and financial resources in the research and development of bremelanotide for HSDD, which is currently our lead product candidate. We completed the last patient visit in the double blind efficacy portion of our Phase 3 RECONNECT STUDY for bremelanotide for HSDD and subsequent to the end of the quarter released top-line results. The top-line results show that both Phase 3 trials in the RECONNECT STUDY of bremelanotide for HSDD in premenopausal women met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments. Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of bremelanotide for HSDD, as well as any future product candidates. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

timely completion of, or need to conduct additional, clinical trials, including for bremelanotide for HSDD, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third-party contractors;

our ability to demonstrate to the satisfaction of the FDA the safety and efficacy of bremelanotide for HSDD or any future product candidates through clinical trials;

whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of bremelanotide for HSDD or any future product candidates;

the acceptance of parameters for regulatory approval, including our proposed indication, primary endpoint assessment and primary endpoint measurement, relating to our lead indications of bremelanotide for HSDD;

our success in educating physicians and patients about the benefits, administration and use of bremelanotide for HSDD or any future product candidates, if approved;

the prevalence and severity of adverse events experienced with bremelanotide for HSDD or any future product candidates or approved products;

the adequacy and regulatory compliance of the autoinjector device, supplied by an unaffiliated third party, to be used as part of our bremelanotide combination product;

the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

our ability to raise additional capital on acceptable terms to achieve our goals;

achieving and maintaining compliance with all regulatory requirements applicable to bremelanotide for HSDD or any future product candidates or approved products;

the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;

the effectiveness of our own or our future potential strategic collaborators' marketing, sales and distribution strategy and operations;

our ability to manufacture clinical trial supplies of bremelanotide for HSDD or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current GMP;

our ability to successfully commercialize bremelanotide for HSDD or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;

our ability to enforce our intellectual property rights in and to bremelanotide for HSDD or any future product candidates;

our ability to avoid third-party patent interference or intellectual property infringement claims;

acceptance of bremelanotide for HSDD or any future product candidates, if approved, as safe and effective by patients and the medical community; and

a continued acceptable safety profile and efficacy of bremelanotide for HSDD or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of bremelanotide for HSDD or any future product candidate to continue our business. In addition to preventing us from executing our current business plan, any delays in our clinical trials, or inability to successfully commercialize our products could impair our reputation in the industry and the investment community, and could hinder our ability to fulfill our existing contractual commitments. As a result, our share price would likely decline significantly, and we would have difficulty raising necessary capital for future projects.

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:

| Exhibit Number | Description | Filed Herewith | Form | Filing Date | SEC File No. |
|---|---|---|---|---|---|
| 31.1 | Certification of Chief Executive Officer. | X | | | |
| 31.2 | Certification of Chief Financial Officer. | X | | | |
| 32.1 | Certification of principal executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | X | | | |
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| 101.INS | XBRL Instance Document. | X | | | |
| 101.SCH | XBRL Taxonomy Extension Schema Document. | X | | | |

| | | |
|---|---|---|
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. | X |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. | X |

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.<br>(Registrant) |
| Date: November 14, 2016 | /s/ Carl Spana<br>Carl Spana, Ph.D.<br>President and<br>Chief Executive Officer (Principal Executive Officer) |
| Date: November 14, 2016 | /s/ Stephen T. Wills<br>Stephen T. Wills, CPA, MST<br>Executive Vice President, Chief Financial Officer and Chief Operating Officer<br>(Principal Financial and Accounting Officer) |

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