

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10 - Q

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

For the quarterly period ended September 30, 2019

or

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

For the transition period from _____ to _____

Commission file number: 001-15543



PALATIN TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

95-4078884

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

**4B Cedar Brook Drive
Cranbury, New Jersey**

(Address of principal executive offices)

08512

(Zip Code)

(609) 495-2200

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$.01 per share	PTN	NYSE American

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, as amended 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, every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
Emerging growth company <input type="checkbox"/>	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Exchange Act. ☐

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (November 8, 2019): 229,116,104

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Special Note Regarding Forward-Looking Statements

In this Quarterly Report on Form 10-Q (this “Quarterly Report”) references to “we,” “our,” “us,” the “Company” or “Palatin” means Palatin Technologies, Inc. and its subsidiary.

Statements in this Quarterly Report, as well as oral statements that may be made by us or by our officers, directors, or employees acting on our behalf, that are not historical facts constitute “forward-looking statements,” which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”). The forward-looking statements in this Quarterly Report do not constitute guarantees of future performance. Investors are cautioned that statements that are not strictly historical facts contained in this Quarterly Report, including, without limitation, the following are forward looking statements:

our ability, and the ability of our licensees, to successfully commercialize Vyleesi™ (the trade name for bremelanotide) for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (“HSDD”) or obtain approvals in countries other than the United States;

estimates of our expenses, future revenue and capital requirements;

our ability to achieve revenues from the sale of our product candidates, and to achieve and maintain profitability;

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;

our expectations regarding performance of our exclusive licensees of Vyleesi™ for the treatment of premenopausal women with HSDD, which is a type of female sexual dysfunction (“FSD”), including:

- o AMAG Pharmaceuticals, Inc. (“AMAG”) for North America,
- o Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (“Fosun”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., for the territories of the People’s Republic of China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. (collectively, “China”), and
- o Kwangdong Pharmaceutical Co., Ltd. (“Kwangdong”) for the Republic of Korea (“Korea”);

our expectation regarding the timing of regulatory submissions and approvals of Vyleesi for HSDD in jurisdictions outside the United States;

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

our expectations regarding the clinical efficacy and utility of our melanocortin agonist product candidates for treatment of inflammatory and autoimmune related diseases and disorders, including ocular indications;

our ability to compete with other products and technologies treating the same or similar indications as 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;

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 performance and retention of our management team, senior staff professionals, and third-party contractors and consultants;

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

our compliance with federal and state laws and regulations;

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

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

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 as well as competing products and technologies; and

our ability to remain listed on the NYSE American stock exchange.

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 under the caption “Risk Factors” and elsewhere in this Quarterly Report, and any of those made in our other reports filed with the U.S. Securities and Exchange Commission (the “SEC”). Except as required by law, we do not intend, and undertake no obligation, to publicly update forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

Palatin Technologies® is a registered trademark of Palatin Technologies, Inc. Vyleesi™ is a trademark of AMAG Pharmaceuticals, Inc. in North America and of Palatin Technologies, Inc. elsewhere in the world.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2019	June 30, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 96,698,232	\$ 43,510,422
Accounts receivable	97,379	60,265,970
Prepaid expenses and other current assets	597,853	637,289
Total current assets	97,393,464	104,413,681
Property and equipment, net	186,166	141,539
Right-of-use assets	213,065	-
Other assets	179,916	179,916
Total assets	<u>\$ 97,972,611</u>	<u>\$104,735,136</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 57,823	\$ 504,787
Accrued expenses	1,579,460	2,848,692
Notes payable, net of discount	-	332,896
Other current liabilities	213,065	499,517
Total liabilities	<u>1,850,348</u>	<u>4,185,892</u>
Stockholders' equity:		
Preferred stock of \$0.01 par value – authorized 10,000,000 shares; shares issued and outstanding designated as follows:		
Series A Convertible: authorized 264,000 shares: issued and outstanding 4,030 shares as of September 30, 2019 and June 30, 2019	40	40
Common stock of \$0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 227,697,257 shares as of September 30, 2019 and 226,815,363 shares as of June 30, 2019	2,276,973	2,268,154
Additional paid-in capital	394,119,078	394,053,929
Accumulated deficit	(300,273,828)	(295,772,879)
Total stockholders' equity	<u>96,122,263</u>	<u>100,549,244</u>
Total liabilities and stockholders' equity	<u>\$ 97,972,611</u>	<u>\$104,735,136</u>

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	
	2019	2018
REVENUES		
License and contract	\$ 97,379	\$ 34,505
OPERATING EXPENSES		
Research and development	3,127,489	3,622,691
General and administrative	1,832,442	2,040,582
Total operating expenses	4,959,931	5,663,273
Loss from operations	(4,862,552)	(5,628,768)
OTHER INCOME (EXPENSE)		
Investment income	370,654	153,583
Interest expense	(9,051)	(206,871)
Total other income (expense), net	361,603	(53,288)
NET LOSS	\$ (4,500,949)	\$ (5,682,056)
Basic net loss per common share	\$ (0.02)	\$ (0.03)
Diluted net loss per common share	\$ (0.02)	\$ (0.03)
Weighted average number of common shares outstanding used in computing basic net loss per common share	233,113,241	205,009,278
Weighted average number of common shares outstanding used in computing diluted net loss per common share	233,113,241	205,009,278

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

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Stockholders' Equity
(unaudited)

	Preferred Stock		Common Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-in	Deficit	Total
					Capital		
Balance, June 30, 2019	4,030	\$ 40	226,815,363	\$ 2,268,154	\$94,053,929	\$295,772,879	\$100,549,244
Stock-based compensation	-	-	224,000	2,240	825,495	-	827,735
Sale of common stock , net of costs	-	-	657,894	6,579	573,151	-	579,730
Warrant repurchase	-	-	-	-	(1,333,497)	-	(1,333,497)
Net loss	-	-	-	-	-	(4,500,949)	(4,500,949)
Balance, September 30, 2019	<u>4,030</u>	<u>\$ 40</u>	<u>227,697,257</u>	<u>\$ 2,276,973</u>	<u>\$94,119,078</u>	<u>\$300,273,828</u>	<u>\$96,122,263</u>

	Preferred Stock		Common Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-in	Deficit	Total
					Capital		
Balance, June 30, 2018	4,030	\$ 40	200,554,205	\$ 2,005,542	\$57,005,233	\$332,045,906	\$26,964,909
Cumulative effect of accounting change	-	-	-	-	-	500,000	500,000
Stock-based compensation	-	-	319,817	3,198	1,230,387	-	1,233,585
Sale of common stock , net of costs	-	-	2,225,145	22,251	2,200,196	-	2,222,447
Withholding taxes related to restricted stock units	-	-	(67,038)	(670)	(65,322)	-	(65,992)
Net loss	-	-	-	-	-	(5,682,056)	(5,682,056)
Balance, September 30, 2018	<u>4,030</u>	<u>\$ 40</u>	<u>203,032,129</u>	<u>\$ 2,030,321</u>	<u>\$60,370,494</u>	<u>\$337,227,962</u>	<u>\$25,172,893</u>

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,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,500,949)	\$ (5,682,056)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	18,253	14,045
Non-cash interest expense	438	23,581
Decrease in right-of-use asset	72,113	-
Stock-based compensation	827,735	1,233,585
Changes in operating assets and liabilities:		
Accounts receivable	60,168,591	(104,189)
Prepaid expenses and other assets	39,436	93,049
Accounts payable	(446,964)	(1,058,542)
Accrued expenses	(1,269,232)	(82,688)
Operating lease liability	(72,113)	-
Other non-current liabilities	-	25,653
Net cash provided by (used in) operating activities	<u>54,837,308</u>	<u>(5,537,562)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(62,880)	-
Net cash used in investing activities	<u>(62,880)</u>	<u>-</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of withholding taxes related to restricted stock units	-	(65,992)
Payment on notes payable obligations	(832,851)	(2,000,000)
Warrant repurchase	(1,333,497)	-
Proceeds from the sale of common stock, net of costs	<u>579,730</u>	<u>2,222,447</u>
Net cash (used in) provided by financing activities	<u>(1,586,618)</u>	<u>156,455</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	53,187,810	(5,381,107)
CASH AND CASH EQUIVALENTS, beginning of period	<u>43,510,422</u>	<u>38,000,171</u>
CASH AND CASH EQUIVALENTS, end of period	<u>\$ 96,698,232</u>	<u>\$ 32,619,064</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	\$ 8,132	\$ 157,636
Cash paid for income taxes	-	-

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 specialized biopharmaceutical company developing first-in-class medicines based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. The Company's product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential.

Melanocortin Receptor System. The melanocortin receptor ("MCr") system is hormone driven, with effects on food intake, metabolism, sexual function, inflammation and immune system responses. There are five melanocortin receptors, MC1r through MC5r. Modulation of these receptors, through use of receptor-specific agonists, which activate receptor function, or receptor-specific antagonists, which block receptor function, can have significant pharmacological effects.

The Company's lead product, Vyleesi™, was approved by the U.S. Food and Drug Administration ("FDA") in June 2019 and is being marketed in North America by AMAG Pharmaceuticals, Inc. ("AMAG") for the treatment of hypoactive sexual desire disorder ("HSDD") in premenopausal women.

The Company's new product development activities focus primarily on MC1r agonists, with potential to treat inflammatory and autoimmune diseases such as dry eye disease, which is also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. The Company believes that the MC1r agonist peptides in development have broad anti-inflammatory effects and appear to utilize mechanisms engaged by the endogenous melanocortin system in regulation of the immune system and resolution of inflammatory responses. The Company is also developing peptides that are active at more than one melanocortin receptor, and MC4r peptide and small molecule agonists with potential utility in obesity and metabolic-related disorders, including rare disease and orphan indications.

Natriuretic Peptide Receptor System. The natriuretic peptide receptor ("NPR") system regulates cardiovascular functions, and therapeutic agents modulating this system have potential to treat cardiovascular and fibrotic diseases. The Company has designed and is developing potential NPR candidate drugs selective for one or more different natriuretic peptide receptors, including natriuretic peptide receptor-A ("NPR-A"), natriuretic peptide receptor B ("NPR-B"), and natriuretic peptide receptor C ("NPR-C").

Business Risk and Liquidity - 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, 2019 of \$300,273,828 and a net loss for the three months ended September 30, 2019 of \$4,500,949, and the Company anticipates incurring significant expenses in the future as a result of spending on its development programs and will require substantial additional financing or revenues to continue to fund its planned developmental activities. To achieve sustained 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 sustained profitability is highly uncertain, and the Company may never be able to achieve profitability on a sustained basis, if at all.

As of September 30, 2019, the Company's cash and cash equivalents were \$96,698,232 and current liabilities were \$1,850,348. Management intends to utilize existing capital resources for general corporate purposes and working capital, including preclinical and clinical development of the Company's MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

Management believes that the Company's existing capital resources will be adequate to fund the Company's planned operations through at least calendar year 2021. The Company will 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 could be materially adversely affected.

**PALATIN TECHNOLOGIES, INC.
and Subsidiary**

Notes to Consolidated Financial Statements
(unaudited)

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. 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, 2019, the Company reported \$97,379 in revenue related to a license agreement with AMAG for Vyleesi for North America ("AMAG License Agreement") (Note 5). For the three months ended September 30, 2018, the Company reported \$34,505 in revenue related to the AMAG License Agreement.

(2) BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") 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, 2019 may not necessarily be indicative of the results of operations expected for the full year.

The accompanying unaudited 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, 2019, filed with the Securities and Exchange Commission ("SEC"), which includes consolidated financial statements as of June 30, 2019 and 2018 and for each of the fiscal years in the three-year period ended June 30, 2019.

(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 U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts 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 \$96,520,597 and \$43,381,556 in a money market account at September 30, 2019 and June 30, 2019, respectively.

Fair Value of Financial Instruments – The Company's financial instruments consist primarily of cash equivalents, accounts receivable and accounts payable. Management believes that the carrying values of cash equivalents, accounts receivable and accounts payable are representative of their respective fair values based on the short-term nature of these instruments.

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 balances insured 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. Accumulated depreciation and amortization was \$2,406,896 and \$2,388,644 as of September 30, 2019 and June 30, 2019, respectively.

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

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 – In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers* (“ASC Topic 606”), which, along with amendments from 2015 and 2016 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. ASC Topic 606 replaced most existing revenue recognition guidance in U.S. GAAP when it became effective.

On July 1, 2018, the Company adopted ASC Topic 606 using the modified retrospective approach, a practical expedient permitted under ASC Topic 606, and applied this approach only to contracts that were not completed as of July 1, 2018.

For licenses of intellectual property, the Company assesses, at contract inception, whether the intellectual property is distinct from other performance obligations identified in the arrangement. If the licensing of intellectual property is determined to be distinct, revenue is recognized for nonrefundable, upfront license fees when the license is transferred to the customer and the customer can use and benefit from the license. If the licensing of intellectual property is determined not to be distinct, then the license will be bundled with other promises in the arrangement into one performance obligation. The Company needs to determine if the bundled performance obligation is satisfied over time or at a point in time. If the Company concludes that the nonrefundable, upfront license fees will be recognized over time, the Company will need to assess the appropriate method of measuring proportional performance.

Regulatory milestone payments are excluded from the transaction price due to the inability to estimate the probability of reversal. Revenue relating to achievement of these milestones is recognized in the period in which the milestone is achieved.

Sales-based royalty and milestone payments resulting from customer contracts solely or predominately for the license of intellectual property will only be recognized upon occurrence of the underlying sale or achievement of the sales milestone and such sales-based royalties and milestone payments are recognized in the same period earned.

The Company recognizes revenue for reimbursements of research and development costs under collaboration agreements as the services are performed. The Company records these reimbursements as revenue and not as a reduction of research and development expenses as the Company is the principal in the research and development activities based upon its control of such activities, which is considered part of its ordinary activities.

Development milestone payments are generally due 30 business days after the milestone is achieved. Sales milestone payments are generally due 45 business days after the calendar year in which the sales milestone is achieved. Royalty payments are generally due on a quarterly basis 20 business days after being invoiced.

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 the Company’s development activities. The Company reviews the activities performed under all contracts each quarter and accrues expenses and the amount of any reimbursement to be received from its 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 the Company does not identify services performed for it but not billed by the service-provider, or if it underestimates or overestimates the value of services performed as of a given date, reported expenses will be understated or overstated.

**PALATIN TECHNOLOGIES, INC.
and Subsidiary**

Notes to Consolidated Financial Statements
(unaudited)

Stock-Based Compensation – The Company charges to expense the fair value of stock options and other equity awards granted. Compensation costs for stock-based awards with time-based vesting are determined using the quoted market price of the Company's common stock on the date of grant or for stock options, the value determined utilizing the Black-Scholes option pricing model, and are recognized on a straight-line basis, while awards containing a market condition are valued using multifactor Monte Carlo simulations. Compensation costs for awards containing a performance condition are determined using the quoted price of the Company's common stock on the date of grant or for stock options, the value is determined utilizing the Black Scholes option pricing model, and are recognized based on the probability of achievement of the performance condition over the service period. Forfeitures are recognized as they occur.

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 and continues to maintain a full valuation allowance against its deferred tax assets based on the history of losses incurred and lack of experience projecting future sales-based royalty and milestone payments.

Net Loss per Common Share - Basic and diluted earnings per common share ("EPS") are calculated in accordance with the provisions of FASB Accounting Standards Codification ("ASC") Topic 260, *Earnings per Share*.

For the three months ended September 30, 2019 and 2018, no additional common shares were added to the computation of diluted EPS because to do so would have been anti-dilutive. The potential number of common shares excluded from diluted EPS during the three months ended September 30, 2019 and 2018 was 37,497,717 and 41,454,308 respectively.

Included in the weighted average common shares used in computing basic and diluted net loss per common share are 5,978,150 and 3,347,999 vested restricted stock units that had not been issued as of September 30, 2019 and 2018, respectively, due to a provision in the restricted stock unit agreements to delay delivery.

(4) NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This update provides clarification on the interaction between Revenue Recognition (Topic 606) and Collaborative Arrangements (Topic 808), including the alignment of unit of account guidance between the two topics. The guidance is effective for public entities for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, with early adoption permitted. The guidance is applicable to the Company beginning July 1, 2020. The Company is currently evaluating the potential effects of this guidance on its consolidated financial statements.

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. The Company is currently evaluating the effect that ASU No. 2016-13 will have on its consolidated financial statements and related disclosures.

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On July 1, 2019, the Company adopted the requirements of ASU No.2016-02, *Leases* ("Topic 842"). The objective of this ASU, along with several related ASUs issued subsequently, is to increase transparency and comparability between organizations that enter into lease agreements. For lessees, the key difference of the new standard from the previous guidance ("Topic 840") is the recognition of a right-of-use ("ROU") asset and lease liability on the balance sheet. The most significant change is the requirement to recognize ROU assets and lease liabilities for leases classified as operating leases. The standard requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. As part of the transition to the new standard, the Company elected to measure and recognize leases that existed at July 1, 2019 using a modified retrospective approach, including the option to not restate comparative periods. For leases existing at the effective date, the Company elected the package of three transition practical expedients and therefore did not reassess whether an arrangement is or contains a lease, did not reassess lease classification, and did not reassess what qualifies as an initial direct cost. Additionally, the Company elected, as practical expedients, not separating lease and non-lease components for all of its leases and the short-term lease recognition exemption for all of its leases that qualify. The Company did not elect the use of the hindsight practical expedient. The adoption of Topic 842 resulted in the recognition of an operating ROU asset and operating lease liability of \$225,134 as of July 1, 2019. The adoption did not have a material impact on the consolidated statements of operations, stockholder's equity and cash flows for the three months ended September 30, 2019.

At lease inception, the Company determines whether an arrangement is or contains a lease. Operating leases are included in operating lease ROU assets, current operating lease liabilities, and noncurrent operating lease liabilities in the consolidated financial statements. ROU assets represent the Company's right to use leased assets over the term of the lease. Lease liabilities represent the Company's contractual obligation to make lease payments over the lease term. For operating leases, ROU assets and lease liabilities are recognized at the commencement date. The lease liability is measured as the present value of the lease payments over the lease term. The Company uses the rate implicit in the lease if it is determinable. When the rate implicit in the lease is not determinable, the Company uses an estimate based on a hypothetical rate provided by a third party as the Company currently does not have issued debt. Operating ROU assets are calculated as the present value of the remaining lease payments plus unamortized initial direct costs plus any prepayments less any unamortized lease incentives received. Lease terms may include renewal or extension options to the extent they are reasonably certain to be exercised. The assessment of whether renewal or extension options are reasonably certain to be exercised is made at lease commencement. Factors considered in determining whether an option is reasonably certain of exercise include, but are not limited to, the value of any leasehold improvements, the value of renewal rates compared to market rates, and the presence of factors that would cause incremental costs to the Company if the option were not exercised. Lease expense is recognized on a straight-line basis over the lease term. The Company has elected not to recognize an ROU asset and obligation for leases with an initial term of twelve months or less. The expense associated with short term leases is included in general and administrative expense in the statement of operations. To the extent a lease arrangement includes both lease and non-lease components, the Company has elected to account for the components as a single lease component.

(5) AGREEMENT WITH AMAG

On January 8, 2017, the Company entered into the AMAG License Agreement. Under the terms of the AMAG License Agreement, the Company granted to AMAG (i) an exclusive license in all countries of North America (the "Territory"), with the right to grant sub-licenses, to research, develop and commercialize products containing Vyleesi (each a "Product", and collectively, "Products"), (ii) a non-exclusive license in the Territory, with the right to grant sub-licenses, to manufacture the Products, and (iii) a non-exclusive license in all countries outside the Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Products.

Following the satisfaction of certain conditions to closing, the license agreement became effective on February 2, 2017. On that date, AMAG paid the Company \$60,000,000 as a one-time initial payment. Pursuant to the terms of and subject to the conditions in the AMAG License Agreement, AMAG was required to reimburse the Company up to an aggregate amount of \$25,000,000 for reasonable, documented, direct out-of-pocket expenses incurred by the Company following February 2, 2017, in connection with the development and regulatory activities necessary to file a New Drug Application ("NDA") for Vyleesi for HSDD in the United States related to Palatin's development obligations.

The Company determined there was no stand-alone value for the license, and that the license and the reimbursable direct out-of-pocket expenses, pursuant to the terms of the License Agreement, represented a combined unit of accounting which totaled \$85,000,000. The Company recognized revenue of the combined unit of accounting over the arrangement using the

input-based proportional method as the Company completed its development obligations. During the three months ended September 30, 2019 and 2018, license and contract revenue included additional billings for AMAG related Vyleesi costs of \$97,379 and \$34,505.

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On June 4, 2018, the FDA accepted the Vyleesi NDA for filing. The FDA's acceptance triggered a \$20,000,000 milestone payment to Palatin from AMAG. As a result, the Company recognized \$20,000,000 in revenue related to regulatory milestones in fiscal 2018. On June 21, 2019, the FDA granted approval of Vyleesi for use in the United States. The FDA's approval triggered a \$60,000,000 milestone payment to Palatin from AMAG. As a result, the Company recognized \$60,000,000 in revenue related to regulatory milestones in fiscal 2019. In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, the Company is eligible to receive from AMAG up to \$300,000,000 in sales milestone payments based on achievement of certain annual net sales for all Products in the Territory.

AMAG is also obligated to pay the Company tiered royalties on annual net sales of Products, on a product-by-product basis, in the Territory ranging from the high single-digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (i) the earliest date on which there are no valid claims of the Company's patent rights covering such Product in such country, (ii) the expiration of the regulatory exclusivity period for such Product in such country and (iii) ten years following the first commercial sale of such Product in such country. Such royalties are subject to reductions in the event that: (a) AMAG must license additional third-party intellectual property in order to develop, manufacture or commercialize a Product, or (b) generic competition occurs with respect to a Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to the Company. After the expiration of the applicable royalties for any Product in a given country, the license for such Product in such country will become a fully paid-up, royalty-free, perpetual and irrevocable license.

The Company engaged Greenhill & Co. LLC ("Greenhill") as the Company's sole financial advisor in connection with a potential transaction with respect to Vyleesi. Under the engagement agreement with Greenhill, the Company is obligated to pay Greenhill a fee equal to 2% of all proceeds and consideration, as defined, paid or to be paid to the Company by AMAG in connection with the AMAG License Agreement, subject to a minimum fee of \$2,500,000. The minimum fee of \$2,500,000, less a credit of \$50,000 for an advisory fee previously paid by the Company, was paid to Greenhill and recorded as an expense upon the closing of the licensing transaction. This amount is credited toward amounts that were and will become due to Greenhill in the future, provided that the aggregate fee payable to Greenhill will not be less than 2% of all proceeds and consideration, as defined, paid or to be paid to the Company by AMAG in connection with the AMAG License Agreement. The Company will generally pay Greenhill 2% of all future proceeds and consideration paid to the Company by AMAG in connection with the AMAG License Agreement, including milestone and royalty payments. The Company also reimbursed Greenhill \$7,263 for certain expenses incurred in connection with its advisory services.

Pursuant to the AMAG License Agreement, the Company has assigned to AMAG the Company's manufacturing and supply agreements with Catalent Belgium S.A. to perform fill, finish and packaging of Vyleesi.

(6) AGREEMENT WITH FOSUN:

On September 6, 2017, the Company entered into a license agreement with Fosun ("Fosun License Agreement") for exclusive rights to commercialize Vyleesi in China. Under the terms of the agreement, the Company received \$4,500,000 in October 2017, which consisted of an upfront payment of \$5,000,000 less \$500,000 that was withheld in accordance with tax withholding requirements in the Chinese Territories and recorded as an expense during the year ended June 30, 2018. The Company will receive a \$7,500,000 milestone payment when regulatory approval in China is obtained, provided that a commercial supply agreement for Vyleesi has been entered into. Palatin has the potential to receive up to \$92,500,000 in additional sales related milestone payments and high single-digit to low double-digit royalties on net sales in the licensed territory. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territory will be the sole responsibility of Fosun.

(7) AGREEMENT WITH KWANGDONG:

On November 21, 2017, the Company entered into a license agreement with Kwangdong ("Kwangdong License Agreement") for exclusive rights to commercialize Vyleesi in Korea.

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Under the terms of the agreement, the Company received \$417,500 in December 2017, consisting of an upfront payment of \$500,000, less \$82,500, which was withheld in accordance with tax withholding requirements in Korea and recorded as an expense during the year ended June 30, 2018. Based upon certain refund provisions, the upfront payment was recorded as non-current deferred revenue at December 31, 2017. On July 1, 2018, in conjunction with the adoption of ASC Topic 606, a one-time transition of adjustment of \$500,000 was recorded to the opening balance of accumulated deficit as the Company determined a significant revenue reversal would not occur in a future period. The Company will receive a \$3,000,000 milestone payment based on the first commercial sale in Korea. Palatin has the potential to receive up to \$37,500,000 in additional sales related milestone payments and mid-single-digit to low double-digit royalties on net sales in the licensed territory. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territory will be the sole responsibility of Kwangdong.

(8) PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	September 30, 2019	June 30, 2019
Clinical study costs	\$ 49,079	\$ 61,798
Insurance premiums	77,856	87,937
Other	470,918	487,554
	<u>\$ 597,853</u>	<u>\$ 637,289</u>

(9) 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's 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, 2019:				
Money Market Account	<u>\$96,520,597</u>	<u>\$96,520,597</u>	<u>\$ -</u>	<u>\$ -</u>
June 30, 2019:				
Money Market Account	<u>\$43,381,556</u>	<u>\$43,831,556</u>	<u>\$ -</u>	<u>\$ -</u>

(10) LEASES

The Company has operating leases of office and laboratory space, each of which expires on June 30, 2020.

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The components of lease expense are as follows:

	Three months ended September 30, 2019
Lease cost	
Operating lease cost	\$ 72,113
Short-term lease cost	8,520
Total lease cost	<u>\$ 80,633</u>

Supplemental balance sheet information related to leases was as follows:

	September 30, 2019
Operating lease ROU asset and liability	<u>\$ 213,065</u>

Supplemental lease term and discount rate information related to leases was as follows:

Weighted -average remaining lease term (years)	0.75
Weighted -average discount rate	6.25%

Supplemental cash flow information related to leases was as follows:

	Three months ended September 30, 2019
Cash paid for the amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	<u>\$ 71,838</u>
Supplemental non-cash information on lease liabilities arising from obtaining right-of-use assets	
Right-of-use assets obtained in exchange for new lease obligation	<u>\$ 56,715</u>

The following table summarizes the maturity of the Company's operating lease liability as of September 30, 2019:

	September 30, 2019
Year Ending June 30, 2020	\$ 217,519
Less imputed interest	(4,454)
Total	<u>\$ 213,065</u>

As of June 30, 2019, the Company had \$225,120 in future lease payments for the year ending June 30, 2020 under ASC Topic 840.

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(11) ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2019	June 30, 2019
Clinical study costs	\$ 171,878	\$ 943,721
Other research related expenses	1,114,475	1,361,414
Professional services	89,138	317,500
Other	203,969	226,057
	<u>\$ 1,579,460</u>	<u>\$ 2,848,692</u>

(12) NOTES PAYABLE:

Notes payable consist of the following:

	June 30, 2019
Notes payable under venture loan	\$ 333,333
Unamortized related debt discount	(295)
Unamortized debt issuance costs	(142)
Notes payable	332,896
Less: current portion	332,896
Long-term portion	<u>\$ -</u>

On December 23, 2014, the Company closed on a \$10,000,000 venture loan which was led by Horizon Technology Finance Corporation ("Horizon"). The debt facility was a four-year senior secured term loan that bore interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50%, and provided for interest-only payments for the first eighteen months followed by monthly payments of principal 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 was amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and included in additional paid-in capital on the Company's balance sheet. In addition, a final incremental payment of \$500,000 was due on January 1, 2019, or upon early repayment of the loan. This final incremental payment was accreted to interest expense over the term of the related debt and included in other liabilities on the consolidated balance sheet. The Company incurred \$209,367 of costs in connection with the loan. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the three months ended December 31, 2018, the loan matured, and on December 31, 2018, the Company made the final incremental payment of \$500,000.

On July 2, 2015, the Company closed on a \$10,000,000 venture loan led by Horizon. The debt facility was a four-year senior secured term loan that bore interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50% and provided for interest-only payments for the first eighteen months followed by monthly payments of principal 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 the Company's common stock exercisable at an exercise price of \$0.91 per share. The Company recorded a debt discount of \$305,196 equal to the fair value of these warrants at issuance, which were amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and was included in additional paid-in capital on the Company's balance sheet. In addition, a final incremental payment of \$500,000 was due on August 1, 2019. This final incremental payment was accreted to interest expense over the term of the related debt and was included in other current liabilities on the consolidated balance sheet. The Company incurred \$146,115 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the three months

ended September 30, 2019, the loan matured, and on July 31, 2019, the Company made the final incremental payment of \$500,000.

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(13) STOCKHOLDERS' EQUITY

Financing Transactions – On June 21, 2019 and April 20, 2018, the Company entered into equity distribution agreements with Canaccord Genuity LLC (“Canaccord”) (the “2019 Equity Distribution Agreement” and the “2018 Equity Distribution Agreement”, respectively), pursuant to which the Company may, from time to time, sell shares of the Company’s common stock at market prices by methods deemed to be an “at-the-market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The 2018 Equity Distribution Agreement and related prospectus was limited to sales of up to an aggregate maximum \$25.0 million of shares of the Company’s common stock, and the 2019 Equity Distribution Agreement and related prospectus is limited to sales of up to an aggregate maximum \$40.0 million of shares of the Company’s common stock. The Company pays Canaccord 3.0% of the gross proceeds as a commission.

For the three months ended September 30, 2019, 657,894 shares of common stock were sold through Canaccord under the 2019 Equity Distribution Agreement for net proceeds of \$579,730 after payment of commission fees of \$19,940 and other related expenses of \$65,000. From inception of the 2019 Equity Distribution Agreement through September 30, 2019, a total of 8,222,469 shares of common Stock were sold for net proceeds of \$10,868,566 after payment of commission fees of \$338,152 and other related expenses of \$65,000. For the three months ended September 30, 2018, 2,225,145 shares of common stock were sold through Canaccord under the 2018 Equity Distribution Agreement for net proceeds of \$2,222,447 after payment of commission fees of \$68,735. From inception of the 2018 Equity Distribution Agreement through September 30, 2019, a total of 18,504,993 shares of common Stock were sold for net proceeds of \$24,249,997 after payment of commission fees of \$750,000, and the 2018 Equity Distribution Agreement is deemed completed.

Stock Purchase Warrants – On September 13, 2019, the Company’s Board of Directors approved a plan to offer to purchase and terminate certain outstanding common stock purchase warrants through privately negotiated transactions. The purchase and termination program has no time limit and may be suspended for periods or discontinued at any time.

During the three months ended September 30, 2019, the Company entered into several warrant termination agreements to repurchase and cancel previously issued Series H and Series J warrants. The Company repurchased and cancelled 474,045 and 2,866,809 Series H and Series J warrants, respectively, at an aggregate buyback price of \$186,773 and \$1,146,724, respectively, plus additional consideration upon any sale of the Company within six months of the respective agreement.

Stock Options – For the three months ended September 30, 2019 and 2018, the Company recorded stock-based compensation related to stock options of \$344,160 and \$323,703, respectively.

In July 2018, the terms of certain options were modified to accelerate vesting and extend the option exercise period. As a result, the Company recorded additional stock-based compensation of \$109,004 during the three months ended September 30, 2018.

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A summary of stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Outstanding - June 30, 2019	14,435,650	0.85	7.3	
Granted	-	-		
Forfeited	-	-		
Exercised	-	-		
Expired	(77,100)	2.72		
Outstanding - September 30, 2019	<u>14,358,550</u>	<u>\$ 0.84</u>	<u>7.1</u>	<u>\$ 2,402,286</u>
Exercisable at September 30, 2019	<u>8,461,000</u>	<u>\$ 0.76</u>	<u>5.9</u>	<u>\$ 1,627,979</u>
Expected to vest at September 30, 2019	<u>5,897,550</u>	<u>\$ 0.96</u>	<u>8.7</u>	<u>\$ 774,907</u>

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

Included in the options outstanding above are 1,075,000 and 117,500 performance-based options granted in December 2017 to executive officers and employees, respectively, which vest during a performance period ending on December 31, 2020, if and upon either i) as to 100% of the target number of shares upon achievement of a closing price for the Company's common stock equal to or greater than \$1.50 per share for 20 consecutive trading days, which is considered a market condition; or ii) as to thirty percent (30%) of the target number of shares, upon the acceptance for filing by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is considered a performance condition; iii) as to fifty percent (50%) of the target number of shares, upon the approval by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is also considered a performance condition; iv) as to twenty percent (20%) of the target number of shares, upon entry into a licensing agreement during the performance period for the commercialization of Vyleesi for FSD in at least two of the following geographic areas (a) four or more countries in Europe, (b) Japan, (c) two or more countries in Central and/or South America, (d) two or more countries in Asia, excluding Japan and China, and (e) Australia, which is also considered a performance condition. The fair value of these options was \$602,760. The Company amortized the fair value over the derived service period of 1.1 years or upon the attainment of the performance condition. Pursuant to the FDA acceptance of the NDA filing of Vyleesi, 30% of the target number of options vested in June 2018 and 50% of the target number of options vested in June 2019 upon FDA approval of Vyleesi.

Restricted Stock Units – For the three months ended September 30, 2019 and 2018, the Company recorded stock-based compensation related to restricted stock units of \$483,575 and \$800,878, respectively.

A summary of restricted stock unit activity is as follows:

	RSU's
Outstanding at July 1, 2019	10,327,833
Granted	-
Forfeited	-
Vested	(224,000)
Outstanding at September 30, 2019	<u>10,103,833</u>

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Included in outstanding restricted stock units in the table above are 5,978,150 vested shares that have not been issued as of September 30, 2019 due to a provision in the restricted stock unit agreements to delay delivery.

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

In June 2019, the Company granted 438,000 performance-based restricted stock units to its executive officers and 182,725 performance-based restricted stock units to other employees which vest during a performance period ending June 24, 2023. The performance-based restricted stock units vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials and licensing of Vyleesi in additional countries or regions.

In December 2017, the Company granted 1,075,000 performance-based restricted stock units to its executive officers and 670,000 performance-based restricted stock units to other employees which vest during a performance period, ending on December 31, 2020, if and upon either i) as to 100% of the target number of shares upon achievement of a closing price for the Company's common stock equal to or greater than \$1.50 per share for 20 consecutive trading days, which is considered a market condition; or ii) as to thirty percent (30%) of the target number of shares, upon the acceptance for filing by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is considered a performance condition; iii) as to fifty percent (50%) of the target number of shares, upon the approval by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is also considered a performance condition; iv) as to twenty percent (20%) of the target number of shares, upon entry into a licensing agreement during the performance period for the commercialization of Vyleesi for FSD in at least two of the following geographic areas (a) four or more countries in Europe, (b) Japan, (c) two or more countries in Central and/or South America, (d) two or more countries in Asia, excluding Japan and China, and (e) Australia, which is also considered a performance condition. The fair value of these awards was \$913,750 and \$569,500, respectively. The Company amortized the fair value over the derived service period of 1.1 years or upon the attainment of the performance condition. Pursuant to the FDA acceptance of the NDA filing for Vyleesi, 30% of the target number of shares vested in June 2018. Pursuant to the FDA approval of Vyleesi, 50% of the target number of shares vested in June 2019.

(14) SUBSEQUENT EVENTS

Between October 1, 2019 and November 8, 2019, a total of 1,238,040 shares of the Company's common stock were sold through Canaccord under the 2019 Equity Distribution Agreement for net proceeds of \$1,026,768 after payment of commission fees of \$31,756.

Between October 1, 2019 and November 8, 2019, the Company entered into warrant termination agreements to repurchase and cancel previously issued Series F, Series H and Series J warrants. The Company repurchased and cancelled 297,352, 992,387 and 1,908,234 Series F, Series H and Series J warrants, respectively, at an aggregate buyback price of \$62,712, \$390,600, and \$760,658, respectively, plus additional consideration upon any sale of the Company within six months of the respective agreement.

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, 2019.

The following discussion and analysis contain forward-looking statements within the meaning of the federal securities laws. You are urged to carefully review our description and examples of forward-looking statements included earlier in this Quarterly Report immediately prior to Part I, under the heading "Special Note Regarding Forward-Looking Statements." Forward-looking statements are subject to risk that could cause actual results to differ materially from those expressed in the forward-looking statements. You are urged to carefully review the disclosures we make concerning risks and other factors that may affect our business and operating results, including those made in this Quarterly Report and our Annual Report on Form 10-K for the year ended June 30, 2019, as well as any of those made in our other reports filed with the SEC. You are cautioned not to place undue reliance on the forward-looking statements included herein, which speak only as of the date of this document. We do not intend, and undertake no obligation, to publish revised forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

Critical Accounting Policies and Estimates

Except for the adoption of Accounting Standards Codification ("ASC") Topic 842, 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, 2019, have not changed during the three months ended September 30, 2019. 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 specialized biopharmaceutical company developing first-in-class medicines based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential.

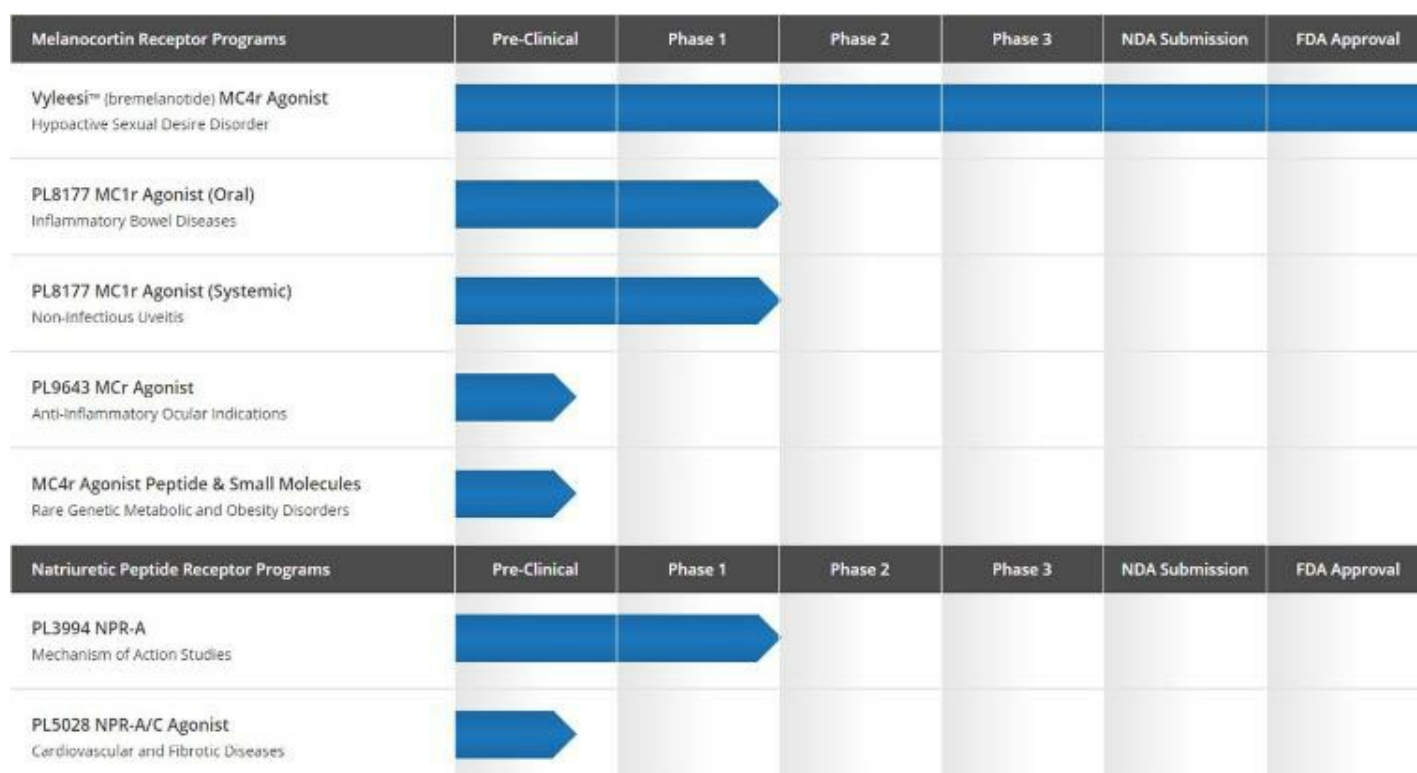
Melanocortin Receptor System. The melanocortin receptor ("MCR") system is hormone driven, with effects on food intake, metabolism, sexual function, inflammation and immune system responses. There are five melanocortin receptors, MC1r through MC5r. Modulation of these receptors, through use of receptor-specific agonists, which activate receptor function, or receptor-specific antagonists, which block receptor function, can have significant pharmacological effects.

Our lead product, Vyleesi™, was approved by the U.S. Food and Drug Administration ("FDA") on June 21, 2019, and is being marketed in North America by AMAG, with product availability in the United States starting in August 2019. Vyleesi is indicated for the treatment of premenopausal women with acquired, generalized HSDD, characterized by low sexual desire that causes marked distress or interpersonal difficulty not due to a co-existing medical or psychiatric condition, relationship problems, or effects of a medication or drug substance.

Our new product development activities focus primarily on MC1r agonists, with potential to treat inflammatory and autoimmune diseases such as dry eye disease, which is also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. We believe that the MC1r agonist peptides we are developing have broad anti-inflammatory effects and appear to utilize mechanisms engaged by the endogenous melanocortin system in regulation of the immune system and resolution of inflammatory responses. We are also developing peptides that are active at more than one melanocortin receptor, and MC4r peptide and small molecule agonists with potential utility in obesity and metabolic-related disorders, including rare disease and orphan indications.

Natriuretic Peptide Receptor System. The natriuretic peptide receptor ("NPR") system regulates cardiovascular functions, and therapeutic agents modulating this system have potential to treat fibrotic diseases, cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis, heart failure, acute asthma, pulmonary diseases and hypertension. We have designed and are developing potential NPR candidate drugs selective for one or more different natriuretic peptide receptors, including natriuretic peptide receptor-A ("NPR-A"), natriuretic peptide receptor B ("NPR-B"), and natriuretic peptide receptor C ("NPR-C").

The following chart illustrates the status of our drug development programs and Vyleesi, which has been approved by the FDA for the treatment of premenopausal women with acquired, generalized HSDD.



Our Strategy

Key elements of our business strategy include:

- Maximizing revenue from Vyleesi by supporting our existing licensees and licensing Vyleesi for global areas outside of North America, China and South Korea;

- Assembling and maintaining a team to create, develop and commercialize MCr and NPR products addressing unmet medical needs;

- 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 existing license agreements, as well as any future research, collaboration or license agreements; and

- Completing development and seeking regulatory approval of certain of our other product candidates.

We were incorporated under the laws of the State of Delaware on November 21, 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B Cedar Brook Drive, Cedar Brook Corporate Center, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. We maintain an Internet site at www.palatin.com, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained in it or connected to it are not incorporated into this Quarterly Report on Form 10-Q. The reference to our website is an inactive textual reference only.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC (www.sec.gov).

Results of Operations

Three Months Ended September 30, 2019 Compared to the Three Months Ended September 30, 2018:

Revenue – For the three months ended September 30, 2019, we recognized \$97,379 in license and contract revenue compared to \$34,505 in license and contract revenue for the three months ended September 30, 2018, both pursuant to our license agreement with AMAG.

Research and Development – Research and development expenses were \$3,127,489 for the three months ended September 30, 2019 compared to \$3,622,691 for the three months ended September 30, 2018. The decrease is primarily related to a decrease in salaries and stock-based compensation offset by an increase in spending on our PL-8177 program.

Research and development expenses related to our Vyleesi, PL3994, PL8177, MC1r, MC4r and other preclinical programs were \$2,297,542 for the three months ended September 30, 2019 compared to \$1,944,240 for the three months ended September 30, 2018. The increase is primarily related to an increase in spending on our PL8177 program.

The amounts of project spending above exclude general research and development spending, which was \$829,947 for the three months ended September 30, 2019 compared to \$1,678,451 for the three months ended September 30, 2018. The decrease in general research and development spending is primarily attributable to a decrease in stock-based compensation and salaries.

Cumulative spending from inception to September 30, 2019 was approximately \$310,400,000 on our Vyleesi program and approximately \$144,900,000 on all our other programs (which include PL3994, PL8177, other melanocortin receptor agonists, other discovery programs and terminated programs). Due to various risk factors described in our Annual Report on Form 10-K for the year ended June 30, 2019, under “Risk Factors,” 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, related net cash inflows will be generated.

General and Administrative – General and administrative expenses, which consist mainly of compensation and related costs, were \$1,832,442 for the three months ended September 30, 2019 compared to \$2,040,582 for the three months ended September 30, 2018. The decrease in general and administrative expenses for the three months ended September 30, 2019 is primarily attributable to a decrease in stock-based compensation.

Other Income (Expense) – Total other income (expense), net was \$361,603 for the three months ended September 30, 2019 compared with \$(53,288) for the three months ended September 30, 2018. For the three months ended September 30, 2019, we recognized \$370,654 of investment income offset by \$(9,051) of interest expense primarily related to our venture debt. For the three months ended September 30, 2018 we recognized \$(206,871) of interest expense primarily related to our venture debt offset by \$153,583 of investment income. Interest expense has decreased as we have repaid our venture debt as of July 2019.

Liquidity and Capital Resources

Since inception, we have generally 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 and license 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, 2019, net cash provided by operating activities was \$54,837,308 compared to cash used in operations of \$5,537,562 for the three months ended September 30, 2018. The difference in cash provided by operations for the three months ended September 30, 2019 compared with cash used in operating activities for the three months ended September 30, 2018 was primarily related to the timing of the receipt of payments related to revenue recorded for our license agreement with AMAG, including payments related to the FDA's approval of Vyleesi.

During the three months ended September 30, 2019, net cash used in investing activities was \$62,880 compared to \$0 for the three months ended September 30, 2018. The change in cash used by investing activities is a result of the purchase of property and equipment during the three months ended September 30, 2019.

During the three months ended September 30, 2019, net cash used in financing activities was \$1,586,618, which consisted of payment on notes payable obligations of \$832,851 and repurchase and cancellation of outstanding warrants of \$1,333,497 offset by proceeds from the sale of common stock of \$579,730 in our "at-the-market" offering program. During the three months ended September 30, 2018, net cash provided by financing activities was \$156,455, which consisted of proceeds from the sale of common stock of \$2,222,247 in our "at-the-market" offering program, offset by payment on notes payable obligations of \$2,000,000 and withholding taxes related to restricted stock units of \$65,992.

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. Continued operations are dependent upon our ability to generate future income from existing licenses, to complete equity or debt financing activities and to enter into additional licensing or collaboration arrangements. As of September 30, 2019, our cash and cash equivalents were \$96,698,232 and our current liabilities were \$1,850,348.

We intend to utilize existing capital resources for general corporate purposes and working capital, including Vyleesi, preclinical and clinical development of our MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

We believe that our existing capital resources will be adequate to fund our planned operations through at least calendar year 2021. We will need additional funding to complete required clinical trials for our product candidates and development programs and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA.

We expect to incur significant expenses as we continue our development of natriuretic peptide and MC1r products. These expenses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

Off-Balance Sheet Arrangements

None.

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, 2019. 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.

There have been no material changes to our risk factors disclosed in Part I, Item 1A, of our Annual Report on Form 10-K for the year ended June 30, 2019.

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

(c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

On September 13, 2019, our Board of Directors approved a plan to offer to purchase and terminate outstanding Series F, Series H and Series J common stock purchase warrants through privately negotiated transactions. The purchase and termination program has no time limit and may be suspended for periods or discontinued at any time.

The following table provides information with respect to purchase and termination of common stock purchase warrants by the Company during the fiscal quarter ended September 30, 2019.

Fiscal Month Period	Total Number of Warrant Shares Purchased ⁽¹⁾	Average Price per Warrant Share	Total Number of Warrant Shares Purchased as Part of Publicly Announced Plans or Programs ⁽²⁾	Maximum Number of Warrant Shares that May Yet be Purchased Under Announced Plans or Programs
July 1, 2019 through July 31, 2019	-	-	-	-
August 1, 2019 through August 31, 2019	-	-	-	-
September 1, 2019 through September 30, 2019	3,340,854	\$ 0.40	-	17,706,743
Total	<u>3,340,854</u>	<u>\$ 0.40</u>	<u>-</u>	<u>17,706,743</u>

(1) During the fiscal quarter ended September 30, 2019, we purchased common stock purchase warrants exercisable for an aggregate of 3,340,854 shares of our common stock consisting of 474,045 Series H warrants and 2,866,809 Series J warrants in privately negotiated transactions.

(2) None.

(3) As of September 30, 2019, the maximum number of common stock purchase warrants that may yet be purchased under the plan is 17,706,743. Between October 1, 2019 and November 8, 2019, an additional 3,197,973 warrant shares, consisting of 297,352 Series F warrant shares, 992,387 Series H warrant shares and 1,908,234 Series J warrant shares were purchased at an average price per warrant share of \$0.38.

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			
32.2	Certification of principal financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
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.

(Registrant)

Date: November 12, 2019

/s/ Carl Spana

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

Date: November 12, 2019

/s/ Stephen T. Wills

Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial Officer
and Chief Operating Officer
(Principal Financial and Accounting Officer)