

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## PALATIN TECHNOLOGIES INC

**Form: 10-Q**

**Date Filed: 2019-05-09**

Corporate Issuer CIK: 911216

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 March 31, 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)

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 ☒

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
<b>Common Stock</b>	<b>PTN</b>	<b>NYSE American</b>

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (May 8, 2019): 203,063,429.

**PALATIN TECHNOLOGIES, INC.**  
**Table of Contents**

**Page**

**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements (Unaudited)**

<a href="#"><u>Consolidated Balance Sheets as of March 31, 2019 and June 30, 2018</u></a>	<a href="#"><u>1</u></a>
<a href="#"><u>Consolidated Statements of Operations for the Three and Nine Months Ended March 31, 2019 and 2018</u></a>	<a href="#"><u>2</u></a>
<a href="#"><u>Consolidated Statements of Comprehensive (Loss) Income for the Three and Nine Months Ended March 31, 2019 and 2018</u></a>	<a href="#"><u>3</u></a>
<a href="#"><u>Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended March 31, 2019 and 2018</u></a>	<a href="#"><u>4</u></a>
<a href="#"><u>Consolidated Statements of Cash Flows for the Nine Months Ended March 31, 2019 and 2018</u></a>	<a href="#"><u>6</u></a>
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	<a href="#"><u>7</u></a>
<a href="#"><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	<a href="#"><u>20</u></a>
<a href="#"><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></a>	<a href="#"><u>24</u></a>
<a href="#"><u>Item 4. Controls and Procedures</u></a>	<a href="#"><u>24</u></a>
<b>PART II – OTHER INFORMATION</b>	
<a href="#"><u>Item 1. Legal Proceedings</u></a>	<a href="#"><u>25</u></a>
<a href="#"><u>Item 1A. Risk Factors</u></a>	<a href="#"><u>25</u></a>
<a href="#"><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	<a href="#"><u>25</u></a>
<a href="#"><u>Item 3. Defaults Upon Senior Securities</u></a>	<a href="#"><u>25</u></a>
<a href="#"><u>Item 4. Mine Safety Disclosures</u></a>	<a href="#"><u>25</u></a>
<a href="#"><u>Item 5. Other Information</u></a>	<a href="#"><u>25</u></a>
<a href="#"><u>Item 6. Exhibits</u></a>	<a href="#"><u>26</u></a>
<a href="#"><u>Signatures</u></a>	<a href="#"><u>27</u></a>

---

## Special Note Regarding Forward-Looking Statements

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

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 (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 facts contained in this Quarterly Report on Form 10-Q, including, without limitation, the following are forward looking statements:

- estimates of our expenses, future revenue and capital requirements;
- our ability to achieve and maintain profitability;
- 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 timing of actions by the Food and Drug Administration (“FDA”) on our application for approval of Vyleesi™ (the trade name for bremlanotide) for the treatment of premenopausal women with hypoactive sexual desire disorder (“HSDD”), which is a type of female sexual dysfunction (“FSD”);
- our expectation regarding performance of our exclusive licensees of Vyleesi, 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, the “Chinese Territories”), and
  - o Kwangdong Pharmaceutical Co., Ltd. (“Kwangdong”) for the Republic of Korea (“Korea”);
- the potential for commercialization of Vyleesi for HSDD in North America by AMAG and other product candidates, if approved, by us;
- 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 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 performance of our management team, senior staff professionals, and third-party contractors and consultants;
- 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 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;
- 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 Part II, Item 1A “Risk Factors” and elsewhere in this Quarterly Report, our Annual Report on Form 10-K for the year ended June 30, 2018 and 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.



## Item 1. Financial Statements.

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

	March 31, 2019	June 30, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 19,813,349	\$ 38,000,171
Prepaid expenses and other current assets	697,178	513,688
Total current assets	20,510,527	38,513,859
Property and equipment, net	156,648	164,035
Other assets	338,916	338,916
Total assets	<u>\$ 21,006,091</u>	<u>\$ 39,016,810</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 474,773	\$ 2,223,693
Accrued expenses	2,640,208	2,103,021
Notes payable, net of discount	1,328,973	5,948,763
Other current liabilities	495,169	487,488
Total current liabilities	4,939,123	10,762,965
Notes payable, net of discount	-	332,898
Deferred revenue	-	500,000
Other non-current liabilities	-	456,038
Total liabilities	4,939,123	12,051,901
Stockholders' equity:		
Preferred stock of \$0.01 par value – authorized 10,000,000 shares:		
Series A Convertible: issued and outstanding 4,030 shares as of March 31, 2019 and June 30, 2018	40	40
Common stock of \$0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 203,063,429 shares as of March 31, 2019 and 200,554,205 shares as of June 30, 2018	2,030,634	2,005,542
Additional paid-in capital	362,033,736	357,005,233
Accumulated deficit	(347,997,442)	(332,045,906)
Total stockholders' equity	16,066,968	26,964,909
Total liabilities and stockholders' equity	<u>\$ 21,006,091</u>	<u>\$ 39,016,810</u>

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

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

	<u>Three Months Ended March 31,</u>		<u>Nine Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
REVENUES:				
License and contract	\$ -	\$ 8,962,709	\$ 34,505	\$ 46,516,370
OPERATING EXPENSES:				
Research and development	3,943,982	7,068,849	10,528,329	27,277,830
General and administrative	1,818,796	2,411,302	5,947,943	5,581,066
Total operating expenses	5,762,778	9,480,151	16,476,272	32,858,896
(Loss) income from operations	(5,762,778)	(517,442)	(16,441,767)	13,657,474
OTHER INCOME (EXPENSE):				
Investment income	107,460	86,496	361,212	219,578
Interest expense	(71,812)	(326,983)	(370,981)	(1,175,023)
Total other income (expense), net	35,648	(240,487)	(9,769)	(955,445)
(Loss) income before income taxes	(5,727,130)	(757,929)	(16,451,536)	12,702,029
Income tax benefit	-	18,746	-	192,611
NET (LOSS) INCOME	\$ (5,727,130)	\$ (739,183)	\$ (16,451,536)	\$ 12,894,640
Basic net (loss) income per common share	\$ (0.03)	\$ (0.00)	\$ (0.08)	\$ 0.07
Diluted net (loss) income per common share	\$ (0.03)	\$ (0.00)	\$ (0.08)	\$ 0.06
Weighted average number of common shares outstanding used in computing basic net (loss) income per common share	207,016,304	197,485,758	206,148,695	197,277,286
Weighted average number of common shares outstanding used in computing diluted net (loss) income per common share	207,016,304	197,485,758	206,148,695	202,712,963

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

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

	<u>Three Months Ended March 31,</u>		<u>Nine Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Net (loss) income	\$ (5,727,130)	\$ (739,183)	\$ (16,451,536)	\$ 12,894,640
Other comprehensive income :				
Unrealized gain on available-for-sale investments	<u>-</u>	<u>-</u>	<u>-</u>	<u>590</u>
Total comprehensive (loss) income	<u>\$ (5,727,130)</u>	<u>\$ (739,183)</u>	<u>\$ (16,451,536)</u>	<u>\$ 12,895,230</u>

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	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	
Balance, December 31, 2018	4,030	\$ 40	203,063,429	\$ 2,030,634	\$61,379,336	\$342,270,312	\$21,139,698
Stock-based compensation	-	-	-	-	654,400	-	654,400
Net loss	-	-	-	-	-	(5,727,130)	(5,727,130)
Balance, March 31, 2019	<u>4,030</u>	<u>\$ 40</u>	<u>203,063,429</u>	<u>\$ 2,030,634</u>	<u>\$62,033,736</u>	<u>\$347,997,442</u>	<u>\$16,066,968</u>

	Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	
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	2,863,581	-	2,866,779
Sale of common stock , net of costs	-	-	2,256,445	22,564	2,230,244	-	2,252,808
Withholding taxes related to restricted stock units	-	-	(67,038)	(670)	(65,322)	-	(65,992)
Net loss	-	-	-	-	-	(16,451,536)	(16,451,536)
Balance, March 31, 2019	<u>4,030</u>	<u>\$ 40</u>	<u>203,063,429</u>	<u>\$ 2,030,634</u>	<u>\$62,033,736</u>	<u>\$347,997,442</u>	<u>\$16,066,968</u>

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 Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, December 31, 2017	4,030	\$ 40	195,373,239	\$ 1,953,732	\$350,787,078	\$ -	\$343,114,797	\$ 9,626,053
Stock-based compensation	-	-	75,158	752	1,328,320	-	-	1,329,072
Withholding taxes related to restricted stock units	-	-	(27,465)	(275)	(20,511)	-	-	(20,786)
Option exercises	-	-	56,400	564	30,667	-	-	31,231
Net loss	-	-	-	-	-	-	(739,183)	(739,183)
Balance, March 31, 2018	<u>4,030</u>	<u>\$ 40</u>	<u>195,477,332</u>	<u>\$ 1,954,773</u>	<u>\$352,125,554</u>	<u>\$ -</u>	<u>\$343,853,980</u>	<u>\$10,226,387</u>

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance, June 30, 2017	4,030	\$ 40	160,515,361	\$ 1,605,153	\$349,974,538	\$ (590)	\$356,743,785	\$ (5,164,644)
Cumulative effect of accounting change	-	-	-	-	4,835	-	(4,835)	-
Stock-based compensation	-	-	150,229	1,503	2,369,469	-	-	2,370,972
Withholding taxes related to restricted stock units	-	-	(27,465)	(275)	(20,511)	-	-	(20,786)
Warrant exercises	-	-	34,782,807	347,828	(233,444)	-	-	114,384
Option exercises	-	-	56,400	564	30,667	-	-	31,231
Unrealized gains on investments	-	-	-	-	-	590	-	590
Net income	-	-	-	-	-	-	12,894,640	12,894,640
Balance, March 31, 2018	<u>4,030</u>	<u>\$ 40</u>	<u>195,477,332</u>	<u>\$ 1,954,773</u>	<u>\$352,125,554</u>	<u>-</u>	<u>\$343,853,980</u>	<u>\$10,226,387</u>

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

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

	<b>Nine Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net (loss) income	\$ (16,451,536)	\$ 12,894,640
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	43,526	42,573
Non-cash interest expense	47,312	143,837
Stock-based compensation	2,866,779	2,370,972
Deferred income tax benefit	-	(500,000)
Changes in operating assets and liabilities:		
Accounts receivable	-	15,116,822
Prepaid expenses and other assets	(183,490)	309,766
Accounts payable	(1,748,920)	(757,725)
Accrued expenses	537,187	(4,601,842)
Deferred revenue	-	(33,965,053)
Other liabilities	51,643	155,218
Net cash used in operating activities	<u>(14,837,499)</u>	<u>(8,790,792)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from maturity of investments	-	250,000
Purchases of property and equipment	(36,139)	(9,500)
Net cash (used in) provided by investing activities	<u>(36,139)</u>	<u>240,500</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payments on capital lease obligations	-	(14,324)
Payment of withholding taxes related to restricted stock units	(65,992)	(45,165)
Payment on notes payable obligations	(5,500,000)	(6,000,000)
Proceeds from the exercise of common stock warrants	-	114,384
Proceeds from the exercise of stock options	-	31,231
Proceeds from the sale of common stock, net of costs	2,252,808	-
Net cash used in financing activities	<u>(3,313,184)</u>	<u>(5,913,874)</u>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(18,186,822)</b>	<b>(14,464,166)</b>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<b><u>38,000,171</u></b>	<b><u>40,200,324</u></b>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<b><u>\$ 19,813,349</u></b>	<b><u>\$ 25,736,158</u></b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 316,159	\$ 876,394
Cash paid for income taxes	-	500,000

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

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. Palatin's product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. The most advanced product candidate is Vyleesi™, the trade name for bremelanotide, a peptide melanocortin receptor 4 ("MC4r") agonist, for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder ("HSDD"), which is a type of female sexual dysfunction ("FSD"), defined as low desire with associated distress or interpersonal difficulty.

A New Drug Application ("NDA") has been submitted to the U.S. Food and Drug Administration ("FDA") for Vyleesi by our exclusive North American licensee, AMAG Pharmaceuticals, Inc. ("AMAG"), and accepted for filing by the FDA, with an FDA decision on approval expected in the second quarter of calendar year 2019. Palatin has also licensed rights to Vyleesi to Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun") for the territories of the People's Republic of China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. (collectively, the "Chinese Territories"), and Kwangdong Pharmaceutical Co., Ltd. ("Kwangdong") for the Republic of Korea ("Korea").

Palatin's new product development activities primarily focus on melanocortin receptor 1 ("MC1r") agonists, with potential to treat a number of inflammatory and autoimmune diseases such as dry eye disease, also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. Palatin has also designed and is developing potential natriuretic peptide receptor ("NPR") candidate drugs that are 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"), which may be useful in the treatment of cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis, heart failure, acute asthma, other pulmonary diseases and hypertension.

*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 March 31, 2019 of \$347,997,442 and a net loss for the three and nine months ended March 31, 2019 of \$5,727,130 and \$16,451,536, respectively, 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 March 31, 2019, the Company's cash and cash equivalents were \$19,813,349 and current liabilities were \$4,939,123. The Company intends to utilize existing capital resources for general corporate purposes and working capital, including preclinical and clinical development of our MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

Management believes that the Company's existing capital resources, together with proceeds received from sales of common stock in the Company's "at-the-market" program (if any), will be adequate to fund the Company's planned operations through at least May 31, 2020. 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 would be materially adversely affected.

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 nine months ended March 31, 2019, the Company reported \$34,505 in license and contract revenue related to a license agreement with AMAG for Vyleesi for North America ("AMAG License Agreement") (Note 5). For the three and nine months ended March 31, 2018, the Company reported \$8,962,709 and \$41,516,370, respectively, in license and contract revenue related to the AMAG License Agreement. In addition, for the nine months ended March 31, 2018, the Company reported \$5,000,000 in license revenue related to a license agreement with Fosun (the "Fosun License Agreement") (Note 6).

*Trading* – The Company's common stock is listed on the NYSE American under the symbol "PTN".

**(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 and nine months ended March 31, 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, 2018, filed with the Securities and Exchange Commission ("SEC"), which includes consolidated financial statements as of June 30, 2018 and 2017 and for each of the fiscal years in the three-year period ended June 30, 2018.

**(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 \$19,645,741 and \$37,808,099 in a money market account at March 31, 2019 and June 30, 2018, respectively.

*Fair Value of Financial Instruments* – The Company's financial instruments consist primarily of cash equivalents, accounts payable and notes payable. Management believes that the carrying values of cash equivalents 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 balances insured by the Federal Depositary 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 \$2,382,085 and \$2,338,558 as of March 31, 2019 and June 30, 2018, respectively.

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. The Company calculated a one-time cumulative transition adjustment of \$500,000 which was recorded on July 1, 2018 to the opening balance of accumulated deficit related to its license agreement with Kwangdong (the “Kwangdong License Agreement”) as the Company determined a significant revenue reversal would not occur in a future period. The one-time adjustment consisted of the recognition of \$500,000 of deferred revenue.

*Revenue Recognition for Periods Prior to July 1, 2018*

The Company has generated revenue solely through license and collaboration agreements. Prior to July 1, 2018, the Company recognized revenue in accordance with FASB ASC Topic 605-25, *Revenue Recognition for Arrangements with Multiple Elements*, which addressed the determination of whether an arrangement involving multiple deliverables contained more than one unit of accounting. A delivered item within an arrangement was considered a separate unit of accounting only if both of the following criteria were met:

- the delivered item had value to the customer on a stand-alone basis; and
- if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered item was considered probable and substantially in control of the vendor.

Under FASB ASC Topic 605-25, if both of the criteria above were not met, then separate accounting for the individual deliverables was not appropriate.

The Company determined that it was appropriate to recognize such revenue using the input-based proportional method during the period of Palatin's development obligations as defined in the AMAG License Agreement. Refer to Note 5 for additional information.

Under the Fosun License Agreement (Note 6), the Company received consideration in the form of an upfront license fee payment and determined that it was appropriate to recognize such consideration as revenue in the first quarter of fiscal year 2018, which was the quarter in which the license was granted, since the license had stand-alone value and the upfront payment received by the Company was non-refundable.

Under the Kwangdong License Agreement (Note 7), the Company received consideration in the form of an upfront license fee payment and determined that it was appropriate to record such consideration as deferred revenue because the upfront payment received by the Company is subject to certain refund provisions.

Revenue resulting from the achievement of development milestones was recorded in accordance with the accounting guidance for the milestone method of revenue recognition. Amounts received prior to satisfying the revenue recognition criteria were recorded as deferred revenue on the Company's consolidated balance sheet.

**Notes to Consolidated Financial Statements**  
(unaudited)

*Revenue Recognition for Periods Commencing 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 will be 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 in the future and such sales-based royalties and milestone payments will be 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.

The cumulative effect of applying ASC Topic 606 to the Company's consolidated balance sheet was as follows:

	Balance at June 30, 2018	Net Adjustment	Balance at July 1, 2018
Deferred revenue	\$ 500,000	\$ (500,000)	\$ -
Accumulated deficit	(332,045,906)	500,000	(331,545,906)

**Notes to Consolidated Financial Statements**  
(unaudited)

The impact of adoption of ASC Topic 606 on the Company's consolidated balance sheet as of March 31, 2019 is as follows:

	As reported March 31, 2019	Adjustments	As reported without adoption of ASC Topic 606
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents	\$ 19,813,349	\$ -	\$ 19,813,349
Prepaid expenses and other current assets	697,178	-	697,178
Total current assets	20,510,527	-	20,510,527
Property and equipment, net	156,648	-	156,648
Other assets	338,916	-	338,916
Total assets	<u>\$ 21,006,091</u>	<u>\$ -</u>	<u>\$ 21,006,091</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable	\$ 474,773	\$ -	\$ 474,773
Accrued expenses	2,640,208	-	2,640,208
Notes payable, net of discount	1,328,973	-	1,328,973
Other current liabilities	495,169	-	495,169
Total current liabilities	4,939,123	-	4,939,123
Notes payable, net of discount	-	-	-
Deferred revenue	-	500,000	500,000
Other non-current liabilities	-	-	-
Total liabilities	4,939,123	500,000	5,439,123
Stockholders' equity:			
Preferred stock	40	-	40
Common stock	2,030,634	-	2,030,634
Additional paid-in capital	362,033,736	-	362,033,736
Accumulated deficit	(347,997,442)	(500,000)	(348,497,442)
Total stockholders' equity	16,066,968	(500,000)	15,566,968
Total liabilities and stockholders' equity	<u>\$ 21,006,091</u>	<u>\$ -</u>	<u>\$ 21,006,091</u>

ASC Topic 606 did not have an impact on the Company's consolidated statements of operations or cash flows.

*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.

*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.



Notes to Consolidated Financial Statements  
(unaudited)

*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.

On December 22, 2017, the U.S. government enacted wide-ranging tax legislation, the Tax Cuts and Jobs Act (the “2017 Tax Act”). The 2017 Tax Act significantly revises U.S. tax law by, among other provisions, (a) lowering the applicable U.S. federal statutory corporate income tax rate from 35% to 21%, (b) eliminating or reducing certain income tax deductions, such as deductions for interest expense, executive compensation expenses and certain employee expenses, and (c) repealing the federal alternative minimum tax (“AMT”) and providing for the refund of existing AMT credits.

Other provisions enacted include a new provision designed to tax low-taxed income of foreign subsidiaries (i.e., GILTI and a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits from controlled foreign corporations. The Company does not have any foreign subsidiaries, and thus these provisions do not apply.

During the year ended June 30, 2018, the Company recorded income tax expense of \$82,500, which consisted of \$500,000 that was withheld in accordance with tax withholding requirements in the Chinese Territories related to the Fosun License Agreement (Note 6) and \$82,500, which was withheld in accordance with tax withholding requirements in Korea related to the Kwangdong License Agreement (Note 7), offset by an income tax benefit of \$500,000. The tax benefit of \$500,000 resulted from the 2017 Tax Act, under which AMT credits became refundable, and therefore a \$500,000 benefit related to the release of a valuation allowance against an AMT credit was recorded during the three and nine months ended March 2018. The Company’s June 30, 2017 tax return was filed during the three months ended March 31, 2018 and the Company did not incur an AMT liability. As a result, as of March 31, 2019 and June 30, 2018, the Company has a current income tax receivable of \$218,000 and a long-term income tax receivable of \$282,000 from estimated fiscal 2018 AMT that can be refunded in the future.

*Net (Loss) Income per Common Share* - Basic and diluted earnings per common share (“EPS”) are calculated in accordance with the provisions of FASB ASC Topic 260, *Earnings per Share*, which includes guidance pertaining to the warrants issued in connection with the Company’s July 3, 2012, December 23, 2014, and July 2, 2015 private placement offerings and the August 4, 2016 underwritten offering, that were exercisable for nominal consideration and, therefore, to the extent not yet exercised were considered in the computation of basic and diluted net (loss) income per common share. As of November 21, 2017, all warrants exercisable for nominal value had been converted into common stock.

**Notes to Consolidated Financial Statements**  
(unaudited)

The following table is a reconciliation of net (loss) income and the shares used in calculating basic and diluted net (loss) income per common share for the three and nine months ended March 31, 2019 and 2018:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2019	2018	2019	2018
Net (loss) income	\$ (5,727,130)	\$ (739,183)	\$ (16,451,536)	\$ 12,894,640
Denominator:				
Weighted average common shares - Basic	207,016,304	197,485,758	206,148,695	197,277,286
Effect of dilutive shares:				
Common stock equivalents arising from stock options, warrants and conversion of preferred stock	-	-	-	3,610,611
Restricted stock units	-	-	-	1,825,066
Weighted average common shares - Diluted	207,016,304	197,485,758	206,148,695	202,712,963
Net (loss) income per common share:				
Basic	\$ (0.03)	\$ (0.00)	\$ (0.08)	\$ 0.07
Diluted	\$ (0.03)	\$ (0.00)	\$ (0.08)	\$ 0.06

As of March 31, 2018, common shares issuable upon the exercise of outstanding options and warrants, excluding outstanding warrants exercisable for nominal consideration, and the vesting of restricted stock units in an aggregate amount of 1,146,250 shares were excluded from the weighted average number of common shares used in computing diluted net income per common share because they were anti-dilutive during the period or the minimum performance requirements or market conditions had not been met. For the three and nine months ended March 31, 2019 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 and nine months ended March 31, 2019 was 40,819,113.

Included in the weighted average common shares used in computing basic and diluted net income (loss) per common share are 3,952,875 and 2,049,249 vested restricted stock units that had not been issued as of March 31, 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 August 2018, the SEC issued Final Rule 33-10532, Disclosure Update and Simplification, which amends certain disclosure requirements that were redundant, duplicative, overlapping or superseded by other SEC disclosure requirements. The amendments generally eliminated or otherwise reduced certain disclosure requirements of various SEC rules and regulations. However, in some cases, the amendments require additional information to be disclosed, including changes in stockholders' equity in interim periods. The rule is effective 30 days after its publication in the Federal Register. The rule was posted on October 4, 2018. On September 25, 2018, the SEC released guidance advising it will not object to a registrant adopting the requirement to include changes in stockholders' equity in the Form 10-Q for the first quarter beginning after the effective date of the rule. The Company adopted this guidance effective for the period ended September 30, 2018.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending June 30, 2019 and interim periods within that annual period. Early adoption is permitted. The Company adopted this guidance during the nine months ended March 31, 2019. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Notes to Consolidated Financial Statements  
(unaudited)

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 ASU No. 2016-13 will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, relating 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 currently evaluating the impact that ASU No. 2016-02 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 Company adopted this guidance during the nine months ended March 31, 2019. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

**(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 an 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. For the three and nine months ended March 31, 2018 the Company recognized \$8,962,709 and \$41,516,370, respectively, as license and contract revenue. During the nine months ended March 31, 2019 license and contract revenue included additional billings for AMAG related Vyleesi costs of \$34,505.

In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, the Company will be eligible to receive from AMAG (i) up to \$60,000,000 upon FDA approval of Vyleesi, and (ii) up to \$300,000,000 in sales milestone payments based on achievement of certain annual net sales for all Products in the Territory. On June 4, 2018 the FDA accepted the Vyleesi NDA for filing. The NDA was filed on March 23, 2018. 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 for the year ended June 30, 2018.

Notes to Consolidated Financial Statements  
(unaudited)

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 until 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 was obligated to pay Greenhill a fee equal to 2% of all proceeds and consideration 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 will be credited toward amounts that 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 paid to the Company by AMAG in connection with the AMAG License Agreement. The Company will pay Greenhill an aggregate total of 2% of all proceeds and consideration paid to the Company by AMAG in connection with the License Agreement, including future milestone and royalty payments, after crediting the \$2,500,000 that was paid to Greenhill upon entering into the AMAG License Agreement. The Company also reimbursed Greenhill \$7,263 for certain expenses incurred in connection with its advisory services.

Pursuant to the 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 the Fosun License Agreement for exclusive rights to commercialize Vyleesi in the Chinese Territories. 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 Chinese Territories 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 the Kwangdong License Agreement for exclusive rights to commercialize Vyleesi in Korea.

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.

**Notes to Consolidated Financial Statements**  
(unaudited)

**(8) PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets consist of the following:

	March 31, 2019	June 30, 2018
Clinical study costs	\$ 327,871	\$ 145,994
Insurance premiums	7,746	42,605
Other	361,561	325,089
	<u>\$ 697,178</u>	<u>\$ 513,688</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)
March 31, 2019:				
Money market account	\$ 19,645,741	\$ 19,645,741	\$ -	\$ -
June 30, 2018:				
Money market account	\$ 37,808,099	\$ 37,808,099	\$ -	\$ -

**(10) ACCRUED EXPENSES**

Accrued expenses consist of the following:

	March 31, 2019	June 30, 2018
Clinical study costs	\$ 1,902,723	\$ 983,410
Other research related expenses	439,029	590,236
Professional services	40,000	297,731
Severance	180,466	115,362
Other	77,990	116,282
	<u>\$ 2,640,208</u>	<u>\$ 2,103,021</u>

Notes to Consolidated Financial Statements  
(unaudited)

(11) NOTES PAYABLE:

Notes payable consist of the following:

	March 31, 2019	June 30, 2018
Notes payable under venture loan	\$ 1,333,333	\$ 6,333,334
Unamortized related debt discount	(2,948)	(33,535)
Unamortized debt issuance costs	(1,412)	(18,138)
Notes payable	1,328,973	6,281,661
Less: current portion	1,328,973	5,948,763
Long-term portion	\$ -	\$ 332,898

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 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 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 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 is offset against the note payable balance and is included in additional paid-in capital on the Company's balance sheet at March 31, 2019 and June 30, 2018. 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 and is included in other current liabilities on the consolidated balance sheet as of March 31, 2019. The Company incurred \$146,115 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.

The Company's obligations under the 2015 amended and restated loan agreement, which includes the 2015 venture loan, are secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company also agreed to specified limitations on pledging or otherwise encumbering its intellectual property assets. The 2015 amended and restated loan agreement includes 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 March 31, 2019, the Company was in compliance with all of its loan covenants.

Notes to Consolidated Financial Statements  
(unaudited)

(12) STOCKHOLDERS' EQUITY

*Financing Transactions* – On April 20, 2018, the Company entered into an equity distribution agreement (the “Equity Distribution Agreement”) with Canaccord Genuity LLC (“Canaccord”), 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 Company will pay Canaccord 3.0% of the gross proceeds as a commission. For the three and nine months ended March 31, 2019, 0 and 2,256,445 shares of the Company’s common stock were sold through Canaccord under the Equity Distribution Agreement for net proceeds of \$0 and \$2,252,808, respectively, after payment of commission fees of \$0 and \$69,674, respectively.

The Company has no obligation to sell any shares under the Equity Distribution Agreement and may at any time suspend solicitation and offers under the Equity Distribution Agreement.

*Stock Purchase Warrants* – During the nine months ended March 31, 2018, the Company issued 23,344,451 shares of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of \$0.01 per share and received \$114,384 and issued 11,438,356 shares of common stock pursuant to the exercise of warrants at an exercise price of \$0.01 per share.

*Stock Options* – For the three and nine months ended March 31, 2019, the Company recorded stock-based compensation related to stock options of \$244,528 and \$885,935, respectively. For the three and nine months ended March 31, 2018, the Company recorded stock-based compensation related to stock options of \$403,464 and \$767,971, respectively.

In July 2018, the terms of certain options were modified to accelerate vesting and extend the option life. As a result, the Company recorded additional stock-based compensation of \$109,004 during the nine months ended March 31, 2019. There were no such modifications during the nine months ended March 31, 2018.

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 - July 1, 2018	12,775,462	\$ 0.76	7.7	
Granted	-	-		
Forfeited	(164,913)	0.54		
Expired	(129,150)	1.77		
Outstanding - March 31, 2019	<u>12,481,399</u>	<u>\$ 0.75</u>	<u>6.8</u>	<u>\$ 2,950,910</u>
Exercisable at March 31, 2019	<u>6,870,074</u>	<u>\$ 0.78</u>	<u>5.5</u>	<u>\$ 1,560,726</u>
Expected to vest at March 31, 2019	<u>5,611,325</u>	<u>\$ 0.73</u>	<u>8.5</u>	<u>\$ 1,390,184</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.

Notes to Consolidated Financial Statements  
(unaudited)

Included in the options outstanding above are 1,075,000 and 125,000 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 selected countries, 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.

*Restricted Stock Units* – For the three and nine months ended March 31, 2019, the Company recorded stock-based compensation related to restricted stock units of \$409,871 and \$1,871,839, respectively. For the three and nine months ended March 31, 2018, the Company recorded stock-based compensation related to restricted stock units of \$925,608 and \$1,603,001 respectively.

A summary of restricted stock unit activity is as follows:

	<u>Number of RSUs</u>
Outstanding at July 1, 2018	9,323,876
Granted	-
Forfeited	(178,851)
Vested and issued	(319,817)
Outstanding at March 31, 2019	<u>8,825,208</u>

Included in outstanding restricted stock units in the table above are 3,952,875 vested shares that have not been issued as of March 31, 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 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.



## 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, 2018.

### Critical Accounting Policies and Estimates

Except for the adoption of ASC Topic 606, 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, 2018, have not changed during the nine months ended March 31, 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. Our most advanced product candidate is Vyleesi™, the trade name for bremelanotide, a peptide melanocortin receptor 4 (MC4r) agonist, for the treatment of premenopausal women with acquired, generalized HSDD, which is a type of FSD, defined as low desire with associated distress or interpersonal difficulty.

**Vyleesi.** Vyleesi is a subcutaneous injectable product for the treatment of HSDD in premenopausal women. Vyleesi is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). In March 2018, our exclusive North American licensee for Vyleesi, AMAG, submitted an NDA to the FDA for Vyleesi for the treatment of HSDD in premenopausal women, which was accepted for filing and review by the FDA. In November 2018, AMAG announced that the FDA requested additional data assessing 24-hour ambulatory blood pressure with short term daily use of Vyleesi, which study has been completed and data submitted to the FDA. The Prescription Drug User Fee Act ("PDUFA") date for completion of FDA review of the Vyleesi NDA was extended by three months to June 23, 2019. We have also licensed rights to Vyleesi to Fosun for the Chinese Territories and Kwangdong for Korea.

Our Phase 3 studies for HSDD in premenopausal women, called the RECONNECT studies, consisted of two double-blind placebo-controlled, randomized parallel group studies comparing the on demand use of 1.75 mg of Vyleesi versus placebo, in each case, delivered via a subcutaneous auto-injector. Each trial consisted of more than 600 patients randomized in a 1:1 ratio to either the treatment arm or placebo with a 24-week evaluation period. In both clinical trials, Vyleesi 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.

After completing the studies, patients had the option to continue in an open-label safety extension study for an additional 52 weeks. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. In the Phase 3 clinical trials, the most frequent adverse events were nausea, flushing, injection site reactions and headache, which were generally mild-to-moderate in intensity and were transient.

We retain worldwide rights for Vyleesi for HSDD and all other indications outside North America, Korea and the Chinese Territories. We are actively seeking potential partners for marketing and commercialization rights for Vyleesi for HSDD outside the licensed territories. However, we may not be able to enter into suitable agreements with potential partners on acceptable terms, if at all.

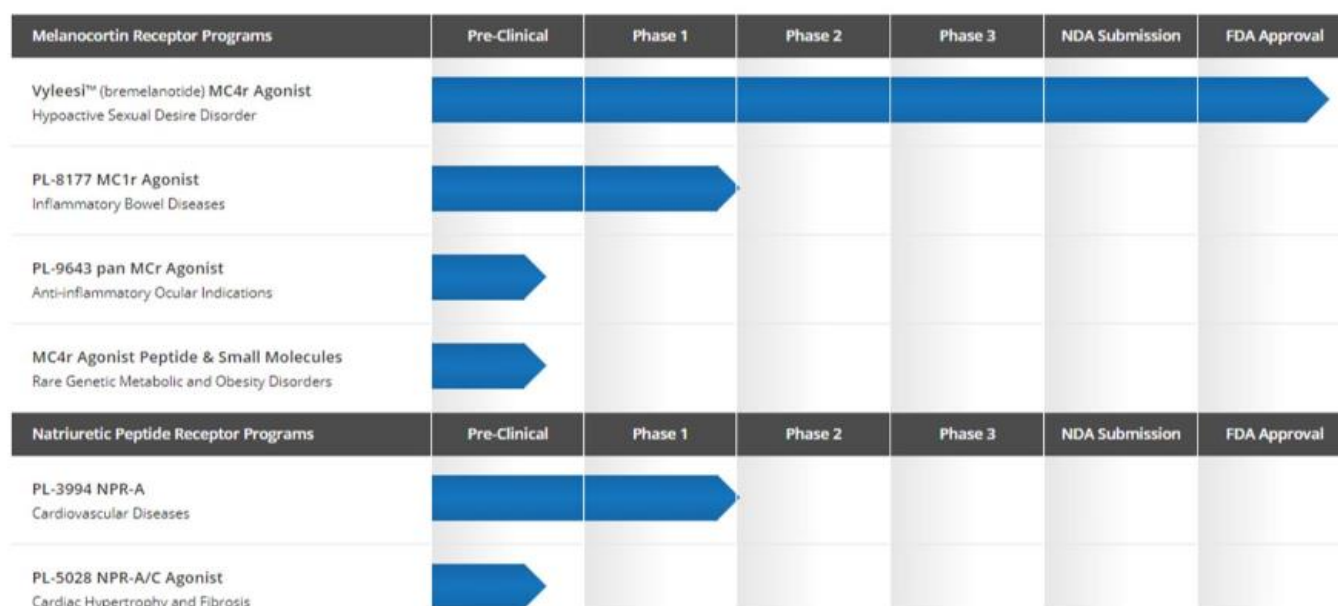
**Melanocortin Receptor Systems.** There are five melanocortin receptors, MC1r through MC5r. Modulation of these receptors, through use of receptor-specific agonists, which activate receptor function, or receptor-specific antagonists, which block receptor function, can have significant pharmacological effects. Our new product development activities primarily focus on MC1r agonists, with potential to treat a number of inflammatory and autoimmune diseases such as dry eye disease, also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. We believe that MC1r agonists, including 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 agonists, with potential utility in a number of obesity and metabolic-related disorders, including rare disease and orphan indications.

- PL-8177, a selective MC1r agonist peptide, is our lead clinical development candidate for inflammatory bowel diseases, including ulcerative colitis, with potential applicability for a number of other diseases. We filed an Investigational New Drug ("IND") application on PL-8177 in late 2017 and have completed subcutaneous dosing of human subjects in a Phase 1 single and multiple ascending dose clinical safety study, with favorable results announced in a press release issued November 8, 2018. We completed a clinical study with oral dosing of PL-8177 in human subjects in the fourth quarter of calendar year 2018, with positive results announced in a press release issued April 4, 2019. Phase 2 clinical trials with oral PL-8177 in ulcerative colitis patients are anticipated to commence in the fourth quarter of calendar year 2019. A phase 2 clinical trial with systemic PL-8177 in non-infectious uveitis, an ocular indication, is also planned to start in the fourth quarter of calendar 2019.
- PL-9643, a pan-melanocortin peptide agonist, is a preclinical development candidate for treating ocular inflammation. We have determined to move forward with PL-9643 rather than PL-8331 because PL-9643 has a significantly later potential patent expiration date and has shown superior results in some preclinical evaluations. We have ongoing IND-enabling preclinical activities with PL-9643, and if results continue to be favorable, we anticipate filing an IND.
- We have initiated preclinical programs with MC4r peptides and orally-active small molecules for treatment of rare genetic metabolic and obesity disorders, and if results are favorable, anticipate selecting a lead clinical development candidate and completing IND-enabling activities in calendar year 2019.

**Natriuretic Peptide Receptor Systems.** The natriuretic peptide receptor ("NPR") system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis, heart failure, acute asthma, other pulmonary diseases and hypertension. While the therapeutic potential of modulating this system is well appreciated, development of therapeutic agents has been difficult due, in part, to the short biological half-life of native peptide agonists. We have designed and are developing potential NPR candidate drugs that are 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").

- PL-3994 is an NPR-A agonist we developed which has completed Phase 1 clinical safety studies. It has potential utility in treatment of a number of cardiovascular diseases, including genetic and orphan diseases resulting from a deficiency of endogenous active NPR-A. We have ongoing academic collaborations with several institutions with PL-3994.
- PL-5028, a dual NPR-A and NPR-C agonist we developed, is in preclinical development for cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis. We have ongoing academic collaborations with several institutions related to PL-5028, and seek to enter into a development partnership by the end of calendar year 2019.

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



## Our Strategy

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 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](http://www.palatin.com), where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained in it or connected to it are not incorporated into this Quarterly Report on Form 10-Q. The reference to our website is an inactive textual reference only.

## Results of Operations

*Three and Nine Months Ended March 31, 2019 Compared to the Three and Nine Months Ended March 31, 2018:*

**Revenue** – For the three and nine months ended March 31, 2019, we recognized \$0 and \$34,505 in revenue pursuant to our license agreement with AMAG compared to \$8,962,709 and \$46,516,370 in revenue for the three and nine months ended March 31, 2018 pursuant to our license agreements with AMAG and Fosun.

On January 8, 2017, we entered into the AMAG License Agreement that provided for \$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 reimbursed us \$25,000,000, less certain expenses directly paid or to be paid by AMAG, for reasonable, documented, direct out-of-pocket expenses we incurred following the effective date of the License Agreement in connection with development and regulatory activities necessary to file an NDA for Vyleesi for HSDD in the United States. For the three and nine months ended March 31, 2018, we recognized \$8,962,709 and \$41,516,370, respectively, of revenue related to this agreement under the input-based proportional method.

On September 6, 2017, we entered into the Fosun License Agreement for exclusive rights to commercialize Vyleesi in the Chinese Territories, which provided for \$5,000,000 as a one-time non-refundable upfront payment, which was recorded as revenue during the nine months ended March 31, 2018. Pursuant to the Fosun License Agreement, \$500,000 was withheld in accordance with tax withholding requirements in the Chinese Territories and was recorded as an expense during the year ended June 30, 2018.

**Research and Development** – Research and development expenses were \$3,943,982 and \$10,528,329, respectively, for the three and nine months ended March 31, 2019 compared to \$7,068,849 and \$27,277,830, respectively for the three and nine months ended March 31, 2018. The decrease related primarily to completion of our Vyleesi Phase 3 clinical trial program and ancillary studies necessary to file an NDA for Vyleesi for HSDD in March 2018.

Research and development expenses related to our Vyleesi, PL-3994, PL-8177, MC1r, MC4r and other preclinical programs were \$3,217,387 and \$7,335,994, respectively, for the three and nine months ended March 31, 2019 compared to \$5,342,113 and \$23,377,721, respectively, for the three and nine months ended March 31, 2018. Spending to date has been primarily related to our Vyleesi for the treatment of HSDD program. The decrease in research and development expenses is mainly attributable to the conclusion of Phase 3 clinical trial and development of Vyleesi for HSDD in March 2018. 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 Vyleesi, PL-8177 and PL-3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which was \$726,595 and \$3,192,335, respectively, for the three and nine months ended March 31, 2019 compared to \$1,726,736 and \$3,900,109, respectively for the three and nine months ended March 31, 2018. The fiscal year to date decrease in general research and development spending is primarily attributable to a decrease in stock-based compensation.

Cumulative spending from inception to March 31, 2019 was approximately \$309,500,000 on our Vyleesi program and approximately \$138,200,000 on all our other programs (which include PL-3994, PL-8177, 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, 2018, 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 \$1,818,796 and \$5,947,943, respectively, for the three and nine months ended March 31, 2019 compared to \$2,411,302 and \$5,581,066, respectively, for the three and nine months ended March 31, 2018. The decrease in general and administrative expenses for the three months ended March 31, 2019 is primarily attributable to a decrease in employee-related expenses. The increase in general and administrative expenses for the nine months ended March 31, 2019 is related to an increase in stock-based compensation.

*Other Income (Expense)* – Total other income (expense), net was \$35,648 and \$(9,769), respectively, for the three and nine months ended March 31, 2019 compared with \$(240,487) and \$(955,445), respectively, for the three and nine months ended March 31, 2018. For the three months ended March 31, 2019, we recognized \$107,460 of investment income offset by \$(71,812) of interest expense primarily related to our venture debt and for the nine months ended March 31, 2019 we recognized \$(370,981) of interest expense offset by \$361,212 of investment income. For the three and nine months ended March 31, 2018 we recognized \$(326,983) and \$(1,175,023), respectively, of interest expense primarily related to our venture debt offset by \$86,496 and \$219,578, respectively, of investment income. Interest expense has decreased as we pay down our venture debt.

*Income Taxes* – No income tax expense was recorded for the three and nine months ended March 31, 2019. Income tax benefit was \$18,746 and \$192,611, respectively, for the three and nine months ended March 31, 2018. For the nine months ended March 31, 2018, the income tax benefit was the result of the release of a valuation allowance during the quarter ended December 31, 2017, offset by income tax expense related to foreign withholding tax requirements. The tax benefit recorded during the three months ended March 31, 2018 was based on the Company's estimated effective tax rate.

### **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 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 nine months ended March 31, 2019, net cash used in operating activities was \$14,837,499 compared to \$8,790,792 for the nine months ended March 31, 2018. The increase in cash used in operations for the nine months ended March 31, 2019 compared with the nine months ended March 31, 2018 was the result of lower cash receipts relating to the AMAG License Agreement.

During the nine months ended March 31, 2019, net cash used in investing activities was \$36,139 compared to cash provided by investing activities of \$240,500 for the nine months ended March 31, 2018. The decrease in cash provided by investing activities and increase in cash used in investing activities for the nine months ended March 31, 2019 compared to the nine months ended March 31, 2018 was the result of proceeds from the maturity of investments during the nine months ended March 31, 2018 and the purchase of property and equipment during the nine months ended March 31, 2019.

During the nine months ended March 31, 2019, net cash used in financing activities was \$3,313,184, which consisted of payment on notes payable obligations of \$5,500,000 and withholding taxes related to restricted stock units of \$65,992 offset by proceeds from the sale of common stock of \$2,252,808 in our "at-the-market" program. During the nine months ended March 31, 2018, net cash used in financing activities was \$5,913,874, which consisted of payments on notes payable obligations of \$6,000,000, withholding taxes related to restricted stock units of \$45,165, and capital lease obligations of \$14,324, offset by proceeds from the exercise of options and warrants of \$145,615.

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 complete equity or debt financing activities and enter into licensing or collaboration arrangements. As of March 31, 2019, our cash and cash equivalents were \$19,813,349 and our current liabilities were \$4,939,123.

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, together with proceeds received from sales of common stock in our "at-the-market" program (if any), will be adequate to fund our planned operations through at least May 31, 2020. We will need additional funding to complete required clinical trials for our product candidates and development programs other than Vyleesi 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. The time required to reach sustained profitability is highly uncertain, and we do not know whether we will be able to achieve profitability on a sustained basis, if at all.

#### **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 March 31, 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, 2018.

### **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.
<a href="#">31.1</a>	Certification of Chief Executive Officer.	X			
<a href="#">31.2</a>	Certification of Chief Financial Officer.	X			
<a href="#">32.1</a>	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			
<a href="#">32.2</a>	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: May 9, 2019

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

Date: May 9, 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)



## Certification of Chief Executive Officer

I, Carl Spana, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Palatin Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Carl Spana

Carl Spana, President and Chief Executive Officer

---

## Certification of Chief Financial Officer

I, Stephen T. Wills, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Palatin Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

/s/ Stephen T. Wills

Stephen T. Wills, Executive Vice President, Chief Financial Officer and Chief Operating Officer

---

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

I, Carl Spana, President and Chief Executive Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the Quarterly Report on Form 10-Q for the period ended March 31, 2019 of Palatin Technologies, Inc. (the "Form 10-Q") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: May 9, 2019

/s/ Carl Spana

Carl Spana, President and Chief Executive Officer (Principal Executive Officer)

---

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

I, Stephen T. Wills, Executive Vice President, Chief Financial Officer and Chief Operating Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the Quarterly Report on Form 10-Q for the period ended March 31, 2019 of Palatin Technologies, Inc. (the "Form 10-Q") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: May 9, 2019

/s/ Stephen T. Wills

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

---