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

FORM 10 - O

		FORM 10 - Q	
☑ QUARTERLY REPORT	PURSUANT TO SECTIO	N 13 OR 15(d) OF THE SECU	JRITIES EXCHANGE ACT OF 1934
	For the quar	terly period ended March 31, 20	020
		or	
☐ TRANSITION REPORT	PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SEC	URITIES EXCHANGE ACT OF 1934
	For the transition	n period from to	
	Comm	ission file number: 001-15543	
		IN TECHNOLOGIES, INC. f registrant as specified in its cha	arter)
=	aware		95-4078884
(State or other jurisdiction o	fincorporation or organizat	tion) (I	R.S. Employer Identification No.)
	Brook Drive , New Jersey		08512
	pal executive offices)		(Zip Code)
	_	(609) 495-2200 ephone number, including area red pursuant to Section 12(b) of	
<b>Title of Each Cla</b> Common Stock, par value \$.0		Trading Symbol PTN	Name of Each Exchange on Which Registered NYSE American
	preceding 12 months (or for	such shorter period that the re	Section 13 or 15(d) of the Securities Exchange Act gistrant was required to file such reports), and (2)
	405 of this chapter) during t		e Data File required to be submitted pursuant to such shorter period that the registrant was
	r company. See the definition	ons of "large accelerated filer," "a	a non-accelerated filer, a smaller reporting ccelerated filer," "smaller reporting company," and
Large accelerated filer Non-accelerated filer Emerging growth company		Accelerated filer Smaller reporting con	□ npany □
If an emerging growth company, with any new or revised financial			use the extended transition period for complying (B) of the Exchange Act. □
Indicate by check mark whether	the registrant is a shell com	pany (as defined in Rule 12b-2 o	f the Exchange Act). Yes ☐ No ☑
Indicate the number of shares ou	itstanding of each of the re	gistrant's classes of common sto	ock, as of the latest practicable date (May 8, 2020):

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### **Special Note Regarding Forward-Looking Statements**

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

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

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

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

AMAG Pharmaceuticals, Inc. ("AMAG") for North America,

Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., for the territories of the People's Republic of China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. (collectively, "China"), and

Kwangdong Pharmaceutical Co., Ltd. ("Kwangdong") for the Republic of Korea ("Korea");

the impact of and our expectations regarding AMAG's announcement of its intent to divest Vyleesi and its other woman's healthcare product, Intrarosa® (prasterone);

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

our ability to conduct preclinical studies and clinical trials, have clinical and research materials manufactured, conduct site visits, retain critical employees and attract new employees, and otherwise conduct our business operations in light of the outbreak of COVID-19 coronavirus in the United States and elsewhere in the world;

estimates of our expenses, future revenue and capital requirements;

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

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

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

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

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

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

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

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

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

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

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

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

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

our compliance with federal and state laws and regulations;

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

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

the impact of fluctuations in foreign exchange rates;

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

our ability to adapt to changes in global economic conditions as well as competing products and technologies; and

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

Such forward-looking statements involve risks, uncertainties and other factors that could cause our actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. Our future operating results are subject to risks and uncertainties and are dependent upon many factors, including, without limitation, the risks identified under the caption "Risk Factors" and elsewhere in this Quarterly Report, and any of those made in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC"). Except as required by law, we do not intend, and undertake no obligation, to publicly update forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

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

# **PART I - FINANCIAL INFORMATION**

# Item 1. Financial Statements.

# PALATIN TECHNOLOGIES, INC. and Subsidiary Consolidated Balance Sheets

(unaudited)

	March 31, 2020	June 30, 2019
ASSETS		
Current assets:	± 00.047.260	± 42.540.422
Cash and cash equivalents	\$ 88,947,368	\$ 43,510,422
Accounts receivable	-	60,265,970
Prepaid expenses and other current assets	675,443	637,289
Total current assets	89,622,811	104,413,681
Property and equipment, net	153,660	141,539
Right-of-use assets	98,491	-
Other assets	179,916	179,916
Total assets	\$ 90,054,878	\$ 104,735,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,612,164	\$ 504,787
Accrued expenses	1,657,237	2,848,692
Notes payable, net of discount	-	332,896
Other current liabilities	89,429	499,517
Total current liabilities	3,358,830	4,185,892
Other liabilities	9,062	-
Total liabilities	3,367,892	4,185,892
Stockholders' equity:		
Preferred stock of \$0.01 par value – authorized 10,000,000 shares; shares issued and outstanding		
designated as follows:		
Series A Convertible: authorized 264,000 shares: issued and outstanding 4,030 shares as of March 31,	40	40
2020 and June 30, 2019  Common stack of \$0.01 parvalue, but havined 200,000 aboves.	40	40
Common stock of \$0.01 par value – authorized 300,000,000 shares: issued and outstanding 229,240,596 shares as of March 31, 2020 and 226,815,363 shares as of June 30,		
2019 issued and outstanding 229,240,596 shares as of March 51, 2020 and 226,615,565 shares as of June 30,	2,292,406	2,268,154
Additional paid-in capital	395,294,270	394,053,929
Accumulated deficit	(310,899,730)	(295,772,879)
Total stockholders' equity	86,686,986	100,549,244
Total liabilities and stockholders' equity	\$ 90,054,878	\$ 104,735,136
Total liabilities and stockholders equity	Ψ 30,034,076	¥ 104,733,130

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

(unaudited)

	Three Months I	inded March 31,	Nine Months E	nded March 31,
	2020	2019	2020	2019
REVENUES				
License and contract	\$ -	\$ -	\$ 117,989	\$ 34,505
ODEDATING EVERNING				
OPERATING EXPENSES				
Research and development	3,641,250	3,943,982	10,026,363	10,528,329
General and administrative	2,072,032	1,818,796	6,308,567	5,947,943
Total operating expenses	5,713,282	5,762,778	16,334,930	16,476,272
Loss from operations	(5,713,282)	(5,762,778)	(16,216,941)	(16,441,767)
OTHER INCOME (EXPENSE)				
Investment income	331,285	107,460	1,101,921	361,212
Interest expense	(278)	(71,812)	(11,831)	(370,981)
Total other income (expense), net	331,007	35,648	1,090,090	(9,769)
NET LOSS	\$ (5,382,275)	\$ (5,727,130)	\$ (15,126,851)	\$ (16,451,536)
NET EU33	<del>\$ (5,362,273)</del>	\$ (3,727,130)	<del>\$ (15,120,651)</del>	<del>3 (10,431,330</del> )
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.03)	\$ (0.06)	\$ (0.08)
Weighted average number of common shares outstanding used in				
computing basic and diluted net loss per common share	235,322,087	207,016,304	234,449,813	206,148,695

# PALATIN TECHNOLOGIES, INC. and Subsidiary Consolidated Statements of Stockholders' Equity

(unaudited)

							Additional					
	Preferre	ed Stoci	k	Commo	n S	tock	Paid-in	Accumulated				
	Shares	Amount		Shares Amount		Shares Amount		Shares Amount		Capital	Deficit	Total
Balance, December 31, 2019	4,030	\$	40	229,174,754	\$	2,291,748	\$394,592,802	\$(305,517,455)	\$ 91,367,135			
Stock-based compensation	-		-	65,842		658	701,468	-	702,126			
Net loss	-		-	-		-	-	(5,382,275)	(5,382,275)			
Balance, March 31, 2020	4,030	\$	40	229,240,596	\$	2,292,406	\$395,294,270	\$(310,899,730)	\$ 86,686,986			
		====			_							
							Additional					
	Preferre	ed Stoci	k	Commo	n Si	tock	Paid-in	Accumulated				
	Shares	Am	ount	Shares		Amount	Capital	Deficit	Total			
Balance, June 30, 2019	4,030	\$	40	226,815,363	\$	2,268,154	\$394,053,929	\$(295,772,879)	\$100,549,244			
Stock-based compensation	-		-	589,617		5,896	2,328,901	-	2,334,797			
Withholding taxes related to restricted stock												
units	-		-	(87,179)		(872)	(103,364)	-	(104,236)			
Sale of common stock, net of costs	-		-	1,895,934		18,959	1,562,539	-	1,581,498			
Warrant repurchases	-		-	-		-	(2,547,466)	-	(2,547,466)			
Warrant exercises	-		-	26,861		269	(269)	-	-			
Net loss						<u>-</u>		(15,126,851)	(15,126,851)			
Balance, March 31, 2020	4,030	\$	40	229,240,596	\$	2,292,406	\$395,294,270	\$(310,899,730)	\$ 86,686,986			
				<u> </u>	=							

# PALATIN TECHNOLOGIES, INC. and Subsidiary Consolidated Statements of Stockholders' Equity

(unaudited)

	Preferre	ed Stoc	k	Commo	n St	tock	Additional Paid-in	Accumulated	
	Shares	Am	ount	Shares		Amount	Capital	Deficit	Total
Balance, December 31, 2018	4,030	\$	40	203,063,429	\$	2,030,634	\$361,379,336	\$(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	4,030	\$	40	203,063,429	\$	2,030,634	\$362,033,736	\$(347,997,442)	\$ 16,066,968
					_				
							Additional		
	Preferre	ed Stoc	k	Commo	n St	tock	Paid-in	Accumulated	
	Preferro Shares		k nount	Commo Shares		tock Amount	Paid-in Capital	Accumulated Deficit	Total
Balance, June 30, 2018									<b>Total</b> \$ 26,964,909
Balance, June 30, 2018  Cumulative effect of accounting change	Shares		ount	Shares		Amount	Capital	Deficit	
	Shares		ount	Shares		Amount	Capital	<b>Deficit</b> \$(332,045,906)	\$ 26,964,909
Cumulative effect of accounting change	Shares		ount	<b>Shares</b> 200,554,205		<b>Amount</b> 2,005,542	<b>Capital</b> \$357,005,233	<b>Deficit</b> \$(332,045,906) 500,000	\$ 26,964,909 500,000
Cumulative effect of accounting change Stock-based compensation	Shares		ount	<b>Shares</b> 200,554,205		<b>Amount</b> 2,005,542	<b>Capital</b> \$357,005,233	<b>Deficit</b> \$(332,045,906) 500,000	\$ 26,964,909 500,000
Cumulative effect of accounting change Stock-based compensation Withholding taxes related to restricted stock	Shares		ount	Shares 200,554,205 - 319,817		2,005,542 - 3,198	<b>Capital</b> \$357,005,233 - 2,863,581	<b>Deficit</b> \$(332,045,906) 500,000	\$ 26,964,909 500,000 2,866,779
Cumulative effect of accounting change Stock-based compensation Withholding taxes related to restricted stock units	Shares		ount	Shares 200,554,205 - 319,817 (67,038)		Amount 2,005,542 - 3,198 (670)	<b>Capital</b> \$357,005,233 - 2,863,581 (65,322)	<b>Deficit</b> \$(332,045,906) 500,000	\$ 26,964,909 500,000 2,866,779 (65,992)

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

(unaudited)

	Nine Months Er	ided March 31,
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (15,126,851)	\$ (16,451,536)
Adjustments to reconcile net loss to net cash		
provided by (used in) operating activities:		
Depreciation and amortization	50,759	43,526
Non-cash interest expense	438	47,312
Decrease in right-of-use asset	220,078	-
Stock-based compensation	2,334,797	2,866,779
Changes in operating assets and liabilities:		
Accounts receivable	60,265,970	-
Prepaid expenses and other assets	(38,154)	(183,490)
Accounts payable	1,107,377	(1,748,920)
Accrued expenses	(1,191,455)	537,187
Operating lease liability	(220,078)	-
Other liabilities	-	51,643
Net cash provided by (used in) operating activities	47,402,881	(14,837,499)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(62,880)	(36,139)
Net cash used in investing activities	(62,880)	(36,139)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of withholding taxes related to restricted		
stock units	(104,236)	(65,992)
Payment on notes payable obligations	(832,851)	(5,500,000)
Warrant repurchases	(2,547,466)	(3,300,000)
Proceeds from the sale of common stock,	(2,347,400)	-
net of costs	1,581,498	2,252,808
Net cash used in financing activities	(1,903,055)	(3,313,184)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	45,436,946	(18,186,822)
CASH AND CASH EQUIVALENTS, beginning of period	43,510,422	38,000,171
CASH AND CASH FOUND ENTS and of paried	¢ 00.047.200	¢ 10.012.240
CASH AND CASH EQUIVALENTS, end of period	<u>\$ 88,947,368</u>	\$ 19,813,349
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	\$ 8,132	\$ 316,159

#### **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-inclass medicines based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. The Company's product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential.

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

The Company's lead product, Vyleesi®, was approved by the U.S. Food and Drug Administration ("FDA") in June 2019 and is currently being marketed in North America by AMAG Pharmaceuticals, Inc. ("AMAG") for the treatment of hypoactive sexual desire disorder ("HSDD") in premenopausal women. As disclosed in Note 5, AMAG has announced its plan to divest Vyleesi and another product.

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

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

Business Risks 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, 2020 of \$310,899,730 and a net loss for the three and nine months ended March 31, 2020 of \$5,382,275 and \$15,126,851, 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, 2020, the Company's cash and cash equivalents were \$88,947,368 and current liabilities were \$3,358,830. Management intends to utilize existing capital resources for general corporate purposes and working capital, including preclinical and clinical development of the Company's MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

Management believes that the Company's existing capital resources will be adequate to fund the Company's planned operations through at least March 31, 2022. The Company will need additional funding to complete required clinical trials for its other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required applications to the FDA. If the Company is unable to obtain approval or otherwise advance in the FDA approval process, the Company's ability to sustain its operations could be materially adversely affected.

# **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.

In March 2020, the World Health Organization declared COVID-19, a disease caused by a novel strain of coronavirus, a pandemic. The Company has taken steps to ensure the safety and well-being of its employees and clinical trial patients to comply with guidance from federal, state and local authorities, while working to ensure the sustainability of its business operations as this unprecedented situation continues to evolve.

In mid-March, the Company transitioned to a company-wide work from home policy. Business-critical activities continue to be subject to heightened precautions to ensure safety of employees. The Company continues to assess its policies, business continuity plans and employee support.

The Company continues to evaluate the impact of COVID-19 on the healthcare system and work with contract research organizations supporting its clinical, research, and development programs to mitigate risk to patients and its business and community partners, taking into account regulatory, institutional, and government guidance and policies.

The Company receives a royalty on sales of Vyleesi by our licensees. AMAG is currently selling Vyleesi in the United States, and Fosun and Kwangdong have licenses to sell Vyleesi in China and Korea, respectively. The Company does not know the effect of the COVID-19 coronavirus on sales of Vyleesi in the United States, but it could have a negative impact on sales, which would adversely impact royalty revenues. The COVID-19 coronavirus could adversely impact the time required to obtain regulatory approvals to sell Vyleesi in China and Korea, which would delay when the Company receives royalty income from sales in those countries.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and it has the potential to materially adversely affect its business, financial condition and results of operations and cashflows during fiscal year 2020 and beyond.

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, 2020, the Company reported \$117,989 in revenue, solely related to a license agreement with AMAG for Vyleesi for North America ("AMAG License Agreement") (Note 5). For the nine months ended March 31, 2019, the Company reported \$34,505 in revenue solely related to the AMAG License Agreement.

# (2) BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnote disclosures required to be presented for complete financial statements. In the opinion of management, these consolidated financial statements contain all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation. The results of operations for the three and nine months ended March 31, 2020 may not necessarily be indicative of the results of operations expected for the full year.

The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2019, filed with the Securities and Exchange Commission ("SEC"), which includes consolidated financial statements as of June 30, 2019 and 2018 and for each of the fiscal years in the three-year period ended June 30, 2019.

# (3) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

*Principles of Consolidation* – The consolidated financial statements include the accounts of Palatin and its wholly-owned inactive subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates – The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents – Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a purchased maturity of less than three months. Cash equivalents consist of \$88,736,048 and \$43,381,556 in a money market account at March 31, 2020 and June 30, 2019, respectively.

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

#### **Notes to Consolidated Financial Statements**

(unaudited)

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

Property and Equipment – Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements and includes assets acquired under capital leases. Property and equipment are recorded at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets, generally five years for laboratory and computer equipment, seven years for office furniture and equipment and the lesser of the term of the lease or the useful life for leasehold improvements. Amortization of assets acquired under capital leases is included in depreciation expense. Maintenance and repairs are expensed as incurred while expenditures that extend the useful life of an asset are capitalized. Accumulated depreciation and amortization was \$2,439,403 and \$2,388,644 as of March 31, 2020 and June 30, 2019, respectively.

Impairment of Long-Lived Assets – The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine recoverability of a long-lived asset, management evaluates whether the estimated future undiscounted net cash flows from the asset are less than its carrying amount. If impairment is indicated, the long-lived asset would be written down to fair value. Fair value is determined by an evaluation of available price information at which assets could be bought or sold, including quoted market prices, if available, or the present value of the estimated future cash flows based on reasonable and supportable assumptions.

Revenue Recognition – In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("ASC Topic 606"), which, along with amendments from 2015 and 2016 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASC Topic 606 replaced most existing revenue recognition guidance in U.S. GAAP when it became effective.

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

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

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

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

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

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

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

Accrued Expenses – Third parties perform a significant portion of the Company's development activities. The Company reviews the activities performed under all contracts each quarter and accrues expenses and the amount of any reimbursement to be received from its collaborators based upon the estimated amount of work completed. Estimating the value or stage of completion of certain services requires judgment based on available information. If the Company does not identify services performed for it but not billed by the service-provider, or if it underestimates or overestimates the value of services performed as of a given date, reported expenses will be understated or overstated.

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

Income Taxes – The Company and its subsidiary file consolidated federal and separate-company state income tax returns. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences or operating loss and tax credit carryforwards are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The Company has recorded and continues to maintain a full valuation allowance against its deferred tax assets based on the history of losses incurred and lack of experience projecting future sales-based royalty and milestone payments.

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

For the three and nine months ended March 31, 2020 and 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, 2020 and 2019 was 33,166,477 and 40,819,113 respectively.

Included in the weighted average common shares used in computing basic and diluted net loss per common share are 6,079,250 and 3,952,875 vested restricted stock units that had not been issued as of March 31, 2020 and 2019, respectively, due to a provision in the restricted stock unit agreements to delay delivery.

# (4) NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The guidance is effective for public entities for fiscal years beginning after December 15, 2020, and for interim periods within those fiscal years, with early adoption permitted. The guidance is applicable to the Company beginning July 1, 2021. The Company is currently evaluating the potential effects of this guidance on its consolidated financial statements.

#### **Notes to Consolidated Financial Statements**

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

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

On July 1, 2019, the Company adopted the requirements of ASU No.2016-02, *Leases* ("Topic 842"). The objective of this ASU, along with several related ASUs issued subsequently, is to increase transparency and comparability between organizations that enter into lease agreements. For lessees, the key difference of the new standard from the previous guidance ("Topic 840") is the recognition of a right-of-use ("ROU") asset and lease liability on the balance sheet. The most significant change is the requirement to recognize ROU assets and lease liabilities for leases classified as operating leases. The standard requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. As part of the transition to the new standard, the Company elected to measure and recognize leases that existed at July 1, 2019 using a modified retrospective approach, including the option to not restate comparative periods. For leases existing at the effective date, the Company elected the package of three transition practical expedients and therefore did not reassess whether an arrangement is or contains a lease, did not reassess lease classification, and did not reassess what qualifies as an initial direct cost. Additionally, the Company elected, as practical expedients, not separating lease and non-lease components for all of its leases and the short-term lease recognition exemption for all of its leases that qualify. The Company did not elect the use of the hindsight practical expedient. The adoption of Topic 842 resulted in the recognition of an operating ROU asset and operating lease liability of \$225,134 as of July 1, 2019. The adoption did not have a material impact on the consolidated statements of operations, stockholder's equity and cash flows for the nine months ended March 31, 2020.

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

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# (5) AGREEMENT WITH AMAG

On January 8, 2017, the Company entered into the AMAG License Agreement pursuant to which the Company granted 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 AMAG License Agreement became effective on February 2, 2017, and AMAG paid the Company \$60,000,000 as a one-time initial payment. Under 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 development and regulatory activities necessary to file a New Drug Application ("NDA") for Vyleesi for HSDD in the United States.

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 AMAG License Agreement, represented a combined unit of accounting which totaled \$85,000,000. The Company recognized revenue of the combined unit of accounting over the arrangement using the input-based proportional method as the Company completed its development obligations. During the nine months ended March 31, 2020, license and contract revenue included additional billings for AMAG related Vyleesi costs of \$117,989. During the nine months ended March 31, 2019, license and contract revenue included additional billings for AMAG related Vyleesi costs of \$34,505.

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

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

The Company engaged Greenhill & Co. LLC ("Greenhill") as the Company's sole financial advisor in connection with a potential transaction with respect to Vyleesi. Under the engagement agreement with Greenhill, the Company was obligated to pay Greenhill a fee equal to 2% of all proceeds and consideration, as defined, paid or to be paid to the Company by AMAG in connection with the AMAG License Agreement, subject to a minimum fee of \$2,500,000. The minimum fee of \$2,500,000, less a credit of \$50,000 for an advisory fee previously paid by the Company, was paid to Greenhill and recorded as an expense upon the closing of the licensing transaction. This amount was credited toward amounts that were to become due to Greenhill, provided that the aggregate fee payable to Greenhill would not be less than 2% of all proceeds and consideration, as defined, paid or to be paid to the Company by AMAG in connection with the AMAG License Agreement. On November 21, 2019, the Company and Greenhill mutually agreed to terminate the engagement agreement. As a result, the Company made a final payment to Greenhill of \$625,000, which was recorded in general and administrative expenses during the nine months ended March 31, 2020. The Company has no future payment obligations to Greenhill.

### **Notes to Consolidated Financial Statements**

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

On January 9, 2020, AMAG announced plans to divest Vyleesi and Intrarosa® (prasterone), both women's healthcare products. While AMAG indicated that it has received preliminary expressions of interest to acquire or sublicense rights to these products, there have been no public disclosures of any potential licensees of AMAG's rights to Vyleesi in North America. After FDA approval of Vyleesi in June 2019, AMAG launched Vyleesi nationally in September 2019 through select specialty pharmacies with its maternal and women's health sales force. Under the AMAG License Agreement, AMAG has a contractual obligation to use commercially reasonable efforts to commercialize Vyleesi, and if AMAG materially breaches its obligations, the Company could have the right to terminate the AMAG License Agreement and require AMAG to assign and transfer certain Vyleesi rights to the Company. Under certain circumstances, AMAG's ability to assign the AMAG License Agreement to a third party is contingent on obtaining the consent of the Company, and the assignee must expressly agree to be bound by the AMAG License Agreement.

# (6) AGREEMENT WITH FOSUN:

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

# (7) AGREEMENT WITH KWANGDONG:

On November 21, 2017, the Company entered into a license agreement with Kwangdong ("Kwangdong License Agreement") for exclusive rights to commercialize Vyleesi in Korea. 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 adjustment of \$500,000 was recorded to the opening balance of accumulated deficit as the Company determined a significant revenue reversal would not occur in a future period. The Company will receive a \$3,000,000 milestone payment based on the first commercial sale in Korea. Palatin has the potential to receive up to \$37,500,000 in additional sales related milestone payments and mid-single-digit to low double-digit royalties on net sales in the licensed territory. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territory will be the sole responsibility of Kwangdong.

# (8) PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	N	larch 31	J	une 30,
		2020		2019
Clinical / Regulatory costs	\$	97,020	\$	61,798
Insurance premiums		8,090		87,937
Other		570,333		487,554
	\$	675,443	\$	637,289

### **Notes to Consolidated Financial Statements**

(unaudited)

# (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/observabl inputs (Level 2)	Significant unobservable le inputs(Level 3)
March 31, 2020:			<u> </u>	
Money Market Account	\$ 88,736,048	\$ 88,736,048	\$ -	\$ -
June 30, 2019:				
Money Market Account	\$ 43,381,556	\$ 43,831,556	\$ -	\$ -

# (10) LEASES

The Company has operating leases of office and laboratory space, each of which expires on June 30, 2020. The Company also has operating leases of copier equipment that expire October 15, 2021.

The components of lease expense are as follows:

Lease cost	M	Three months ended March 31, 2020		ne months ended larch 31, 2020
Operating lease cost	\$	53,454	\$	152,712
Variable lease cost		17,824		53,473
Short-term lease cost		3,600		15,720
Total lease cost	\$	74,878	\$	221,905
Supplemental balance sheet information related to leases was as follows:				

	M	arcn 31,
		2020
Operating lease ROU asset and liability	\$	98,491

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

Weighted-average remaining lease term (years)	0.5
Weighted-average discount rate	6.25%

# **Notes to Consolidated Financial Statements**

(unaudited)

Supplemental cash flow information related to leases was as follows:

	 ee months ended arch 31, 2020	 ne months ended larch 31, 2020
Cash paid for the amounts included in the measurement of lease liabilities:	 	
Operating cash flows for operating leases	\$ 77,096	\$ 226,031
Supplemental non-cash information on lease liabilities arising from obtaining right-of-use assets:		,
Right-of-use assets obtained in exchange for new lease obligation	\$ 	\$ 93,435

The following table summarizes the maturity of the Company's operating lease liability as of March 31, 2020:

	 March 31, 2020
Year Ending June 30	 <u> </u>
2020	\$ 77,097
2021	18,360
2022	4,590
Less imputed interest	(1,556)
Total	\$ 98,491

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

# (11) ACCRUED EXPENSES

Accrued expenses consist of the following:

	 March 31, 2020	 June 30, 2019
Clinical / Regulatory costs	\$ 725,858	\$ 943,721
Other research related expenses	799,755	1,361,414
Professional services	32,000	317,500
Other	99,624	226,057
	\$ 1,657,237	\$ 2,848,692

#### **Notes to Consolidated Financial Statements**

(unaudited)

# (12) NOTES PAYABLE:

Notes payable consist of the following:

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

On December 23, 2014, the Company closed on a \$10,000,000 venture loan which was led by Horizon Technology Finance Corporation ("Horizon"). The debt facility was a four-year senior secured term loan that bore interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50%, and provided for interest-only payments for the first eighteen months followed by monthly payments of principal of \$333,333 plus accrued interest through January 1, 2019. The lenders also received five-year immediately exercisable Series D 2014 warrants to purchase 666,666 shares of common stock exercisable at an exercise price of \$0.75 per share. The Company recorded a debt discount of \$267,820 equal to the fair value of these warrants at issuance, which was amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and included in additional paid-in capital on the Company's balance sheet. In addition, a final incremental payment of \$500,000 was due on January 1, 2019, or upon early repayment of the loan. This final incremental payment was accreted to interest expense over the term of the related debt and included in other liabilities on the consolidated balance sheet. The Company incurred \$209,367 of costs in connection with the loan. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the three months ended December 31, 2018, the loan matured, and on December 31, 2018, the Company made the final incremental payment of \$500,000.

On July 2, 2015, the Company closed on a \$10,000,000 venture loan led by Horizon. The debt facility was a four-year senior secured term loan that bore interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50% and provided for interest-only payments for the first eighteen months followed by monthly payments of principal of \$333,333 plus accrued interest through August 1, 2019. The lenders also received five-year immediately exercisable Series G warrants to purchase 549,450 shares of the Company's common stock exercisable at an exercise price of \$0.91 per share. The Company recorded a debt discount of \$305,196 equal to the fair value of these warrants at issuance, which were amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and was included in additional paid-in capital on the Company's balance sheet. In addition, a final incremental payment of \$500,000 was due on August 1, 2019. This final incremental payment was accreted to interest expense over the term of the related debt and was included in other current liabilities on the consolidated balance sheet. The Company incurred \$146,115 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the nine months ended March 31, 2020, the loan matured, and on July 31, 2019, the Company made the final incremental payment of \$500,000.

### **Notes to Consolidated Financial Statements**

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# (13) STOCKHOLDERS' EQUITY

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

For the nine months ended March 31, 2020, 1,895,934 shares of common stock were sold through Canaccord under the 2019 Equity Distribution Agreement for net proceeds of \$1,581,498 after payment of commission fees of \$51,696 and other related expenses of \$90,000. From inception of the 2019 Equity Distribution Agreement through March 31, 2020, a total of 9,460,509 shares of common Stock were sold for net proceeds of \$11,870,334 after payment of commission fees of \$369,907 and other related expenses of \$90,000. For nine months ended March 31, 2019, 2,256,445 shares of the Company's common stock were sold through Canaccord under the 2018 Equity Distribution Agreement for net proceeds of \$2,252,808 after payment of commission fees of \$69,674. From inception of the 2018 Equity Distribution Agreement through June 26, 2019, a total of 18,504,993 shares of common Stock were sold for net proceeds of \$24,249,997 after payment of commission fees of \$750,000, and the 2018 Equity Distribution Agreement is deemed completed.

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

During the nine months ended March 31, 2020, the Company entered into several warrant termination agreements to repurchase and cancel the following previously issued Series F, Series H and Series J warrants for the following aggregate buyback prices, plus additional consideration upon any sale of the Company within six months of the respective agreement:

		2020		
	Warrants	Buyback price		
Series F Warrants	297,352	\$ 62,712		
Series H Warrants	1,466,432	577,373		
Series J Warrants	4,774,889	1,907,381		
	6,538,673	\$ 2,547,466		

During the nine months ended March 31, 2020, the Company issued 26,861 shares of common stock upon the cashless exercise provisions of 666,666 Series D warrants at an exercise price of \$0.75 per share.

Stock Options – For the three and nine months ended March 31, 2020, the Company recorded stock-based compensation related to stock options of \$348,880 and \$1,027,604, respectively. 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.

In July 2018, the terms of certain options were modified to accelerate vesting and extend the option exercise period. As a result, the Company recorded additional stock-based compensation of \$109,004 during the nine months ended March 31, 2019.

### **Notes to Consolidated Financial Statements**

(unaudited)

A summary of stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Outstanding - June 30, 2019	14,435,650	0.85	7.3	
Granted Forfeited Exercised	104,500 (104,537)	0.58 1.03		
Expired	(77,100)	2.72		
Outstanding - March 31, 2020	14,358,513	\$ 0.84	6.6	\$ 146,877
Exercisable at March 31, 2020	9,038,250	\$ 0.77	5.6	\$ 84,309
Expected to vest at March 31, 2020	5,320,263	\$ 0.94	8.3	\$ 62,568

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

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

Restricted Stock Units – For the three and nine months ended March 31, 2020, the Company recorded stock-based compensation related to restricted stock units of \$353,246 and \$1,307,193, respectively. 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.

#### **Notes to Consolidated Financial Statements**

(unaudited)

A summary of restricted stock unit activity is as follows:

	RSUs
Outstanding at July 1, 2019	10,327,833
Granted	-
Forfeited	(123,438)
Vested	(612,275)
Outstanding at March 31, 2020	9,592,120

Included in outstanding restricted stock units in the table above are 6,079,250 vested shares that have not been issued as of March 31, 2020 due to a provision in the restricted stock unit agreements to delay delivery.

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

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

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

# Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes to the consolidated financial statements filed as part of this report and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended June 30, 2019.

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

# **Critical Accounting Policies and Estimates**

Except for the adoption of Accounting Standards Codification ("ASC") Topic 842, our significant accounting policies, which are described in the notes to our consolidated financial statements included in this report and in our Annual Report on Form 10-K for the year ended June 30, 2019, have not changed during the nine months ended March 31, 2020. 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.

In March 2020, the World Health Organization declared COVID-19, a disease caused by a novel strain of coronavirus, a pandemic. We have taken steps to ensure the safety and well-being of our employees and clinical trial patients to comply with guidance from federal, state and local authorities, while working to ensure the sustainability of our business operations as this unprecedented situation continues to evolve.

In mid-March, we transitioned to a company-wide work from home policy. Business-critical activities continue to be subject to heightened precautions to ensure safety of employees. We continue to assess our policies, business continuity plans and employee support.

We continue to evaluate the impact of COVID-19 on the healthcare system and work with contract research organizations supporting our clinical, research, and development programs to mitigate risk to patients and our business and community partners, taking into account regulatory, institutional, and government guidance and policies.

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

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

Our new product development activities focus primarily on MC1r agonists, with potential to treat inflammatory and autoimmune diseases such as dry eye disease, which is also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. An investigational new drug application for PL9643, a peptide we developed, to treat dry eye disease was filed with the FDA in December 2019, and a Phase 2 study commenced in the first quarter of calendar year 2020. While the trial is ongoing, recruitment at additional sites has been delayed because of the COVID-19 coronavirus outbreak. We are in close contact with the contract research organizations ("CROs") and clinical sites conducting the PL9643 clinical trial on our behalf, and believe that if we can restart enrollment in June 2020 we will have top line data in the fourth quarter of calendar year 2020. A Phase 2 proof-of-concept study of PL8177 in ulcerative colitis patients had been anticipated to commence in mid-calendar year 2020. We are in contact with CROs and clinical sites for this study, and while a definitive decision has not yet been made, because of the COVID-19 coronavirus outbreak we anticipate a delay of at least six months in initiating the Phase 2 PL8177 study in ulcerative colitis patients. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to materially adversely affect our business, financial condition and results of operations.

We believe that the MC1r agonist peptides we are developing have broad anti-inflammatory effects and appear to utilize mechanisms engaged by the endogenous melanocortin system in regulation of the immune system and resolution of inflammatory responses. We are also developing peptides that are active at more than one melanocortin receptor, and MC4r peptide and small molecule agonists with potential utility in obesity and metabolic-related disorders, including rare disease and orphan indications.

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

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

# Clinical Pipeline

Melanocortin Receptor Programs	Pre-Clinical	Phase 1	Phase 2	Phase 3	NDA Submission	FDA Approval
Vyleesi® (bremelanotide) MC4r Agonist Hypoactive Sexual Desire Disorder						
PL9643 MCr Agonist Dry Eye Disease						
PL8177 MC1r Agonist (Systemic) Non-Infectious Uveitis			•			
PL8331 MCr Agonist Diabetic Retinopathy						
PL8177 MC1r Agonist (Oral) nflammatory Bowel Diseases						
MC4r Agonist Peptide & Small Molecules Rare Genetic Metabolic and Obesity Disorders						
Natriuretic Peptide Receptor Programs	Pre-Clinical	Phase 1	Phase 2	Phase 3	NDA Submission	FDA Approval
PL3994 NPR-A. Cardiovascular Disease			•			
PL5028 NPR-A/C Agonist Lardiovascular and Fibrotic Diseases						

#### **Our Strategy**

Key elements of our business strategy include:

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

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

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

Partially funding our product development programs with the cash flow generated from existing license agreements, as well as any future research, collaboration or license agreements; and

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

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

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

### **Results of Operations**

Three and Nine months Ended March 31, 2020 Compared to the Three and Nine months Ended March 31, 2019:

Revenue – For the three and nine months ended March 31, 2020, we recognized zero and \$117,989, respectively, in license and contract revenue pursuant to our license agreement with AMAG compared to zero and \$34,505 in revenue for the three and nine months ended March 31, 2019, respectively. Due to the early commercial stage of Vyleesi and the sales and marketing strategy of AMAG, including no charge for the first Vyleesi prescription, AMAG has not generated positive net sales through March 31, 2020, which resulted in no royalties to Palatin during this period. On January 9, 2020, AMAG announced plans to divest Vyleesi. In May 2020, AMAG stated it expects to provide further details on the divesture by the end of the second quarter of this calendar year. See note 5 to our Consolidated Financial Statements.

Research and Development – Research and development expenses were \$3,641,250 and \$10,026,363 for the three and nine months ended March 31, 2020, respectively, compared to \$3,943,982 and \$10,528,329 for the three and nine months ended March 31, 2019, respectively. The decrease for the three and nine months ended March 31, 2020 as compared to the three and nine months ended March 31, 2019 is related to the overall decreases in program spending and compensation related expenses detailed below.

Research and development expenses related to our Vyleesi, PL3994, PL8177, MC1r, MC4r and other preclinical programs were \$2,801,779 and \$7,458,837 for the three and nine months ended March 31, 2020, respectively, compared to \$3,217,387 and \$7,335,994 for the three and nine months ended March 31, 2019, respectively. The decrease for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019 is the result of an overall decrease in spending on our programs primarily relating to our Vyleesi program, offset by an increase in spending on our other melanocortin receptor programs. The increase in spending for the nine months ended March 31, 2020 as compared to the nine months ended March 31, 2019 is a result of increased spending primarily on our melanocortin receptor programs.

The amounts of project spending above exclude general research and development spending, which was \$839,471 and \$2,567,526 for the three and nine months ended March 31, 2020, respectively, compared to \$726,595 and \$3,192,335 for the three and nine months ended March 31, 2019 respectively. The increase in general research and development spending for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 is primarily attributable to an increase in stock-based compensation and salaries. The decrease in general research and development spending for the nine months ended March 31, 2020 compared to the nine months ended March 31, 2019 is primarily attributable to a decrease in stock-based compensation.

Cumulative spending from inception to March 31, 2020 was approximately \$311,000,000 on our Vyleesi program and approximately \$151,200,000 on all our other programs (which include PL3994, PL8177, other melanocortin receptor agonists, other discovery programs and terminated programs). Due to various risk factors described in our Annual Report on Form 10-K for the year ended June 30, 2019, under "Risk Factors," including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and larger-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, related net cash inflows will be generated.

General and Administrative – General and administrative expenses, which consist mainly of compensation and related costs, were \$2,072,032 and \$6,308,567 for the three and nine months ended March 31, 2020, respectively, compared to \$1,818,796 and \$5,947,943 for the three and nine months ended March 31, 2019, respectively. The increase in general and administrative expenses for the three and nine months ended March 31, 2020 is primarily attributable to the final payment made in connection with the Greenhill agreement during the nine months ended March 31, 2020, and professional fees related to the Vyleesi divestiture.

Other Income (Expense) – Total other income (expense), net was \$331,007 and \$1,090,090 for the three and nine months ended March 31, 2020, respectively, compared with \$35,648 and \$(9,769) for the three and nine months ended March 31, 2019, respectively. For the three and nine months ended March 31, 2020, we recognized \$331,285 and \$1,101,921, respectively, of investment income offset by \$278 and \$11,831, respectively, of interest expense primarily related to our venture debt. For the three and nine months ended March 31, 2019, we recognized \$107,460 and \$361,212, respectively, of investment income offset by \$71,812 and \$370,981, respectively, of interest expense primarily related to our venture debt. Interest income has increased as a result of the Company's increased cash position. Interest expense has decreased as we have repaid our venture debt as of July 2019.

### **Liquidity and Capital Resources**

Since inception, we have generally incurred net operating losses, primarily related to spending on our research and development programs. We have financed our net operating losses primarily through debt and equity financings and amounts received under collaborative and license agreements.

Our product candidates are at various stages of development and will require significant further research, development and testing and some may never be successfully developed or commercialized. We may experience uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, which may include unanticipated problems and additional costs relating to:

the development and testing of products in animals and humans;

product approval or clearance;

regulatory compliance;

good manufacturing practices ("GMP") compliance;

intellectual property rights;

product introduction;

marketing, sales and competition; and

obtaining sufficient capital.

Failure to enter into or successfully perform under collaboration agreements and obtain timely regulatory approval for our product candidates and indications would impact our ability to increase revenues and could make it more difficult to attract investment capital for funding our operations. Any of these possibilities could materially and adversely affect our operations and require us to curtail or cease certain programs.

During the nine months ended March 31, 2020, net cash provided by operating activities was \$47,402,881 compared to cash used in operations of \$14,837,499 for the nine months ended March 31, 2019. The difference in cash provided by operations for the nine months ended March 31, 2020 compared with cash used in operating activities for the nine months ended March 31, 2019 was primarily related to the timing of the receipt of payments related to revenue recorded for our license agreement with AMAG, including payments related to the FDA's approval of Vylessi.

During the nine months ended March 31, 2020, net cash used in investing activities was \$62,880 compared to \$36,139 for the nine months ended March 31, 2019 for the purchase of property and equipment.

During the nine months ended March 31, 2020, net cash used in financing activities was \$1,903,055, which consisted of payment on notes payable obligations of \$832,851, repurchase and cancellation of outstanding warrants of \$2,547,466 and payment of withholding taxes related to restricted stock units of \$104,236 offset by net proceeds from the sale of common stock of \$1,581,498 in our "at-the-market" offering program. 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, payment of withholding taxes related to restricted stock units of \$65,992 offset by net proceeds from the sale of common stock of \$2,252,808 in our "at-the-market" offering program.

We have incurred cumulative negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Continued operations are dependent upon our ability to generate future income from existing licenses, to complete equity or debt financing activities and to enter into additional licensing or collaboration arrangements. As of March 31, 2020, our cash and cash equivalents were \$88,947,368 and our current liabilities were \$3,358,830.

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

We believe that our existing capital resources will be adequate to fund our planned operations through at least March 31, 2022. We will need additional funding to complete required clinical trials for our product candidates and development programs and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA. However, the COVID-19 pandemic may negatively impact our operations, including possible effects on our financial condition, ability to access the capital markets on attractive terms or at all, liquidity, operations, suppliers, industry, and workforce. We will continue to evaluate the impact that these events could have on operations, financial position, and the results of operations and cash flows during fiscal year 2020 and beyond.

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

### **Off-Balance Sheet Arrangements**

None.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required to be provided by smaller reporting companies.

### Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2020. 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.

The following information should be read in conjunction with the risk factors and uncertainties disclosed in Part I, Item 1A, of our Annual Report on Form 10-K for the year ended June 30, 2019, filed with the SEC on September 12, 2019. Except as disclosed below, there have been no material changes to our risk factors disclosed in Part I, Item 1A, of our Annual Report on Form 10-K for the year ended June 30, 2019.

# The COVID-19 coronavirus could adversely impact our clinical trials.

Since the initial report of a novel strain of coronavirus, COVID-19, in China in December 2019, the COVID-19 coronavirus has spread to multiple countries, including the United States and European and Asia-Pacific countries. We have active and planned clinical trial sites in the United States and planned clinical trial sites in Europe, and our licensees have planned clinical trial sites in Asia-Pacific countries. As the COVID-19 coronavirus continues to spread around the globe, we will likely experience disruptions that could severely impact our planned clinical trials, including our Phase 2 clinical trial with PL9643 in the United States for dry eye disease, a planned Phase 2 clinical trial with PL8177 for ulcerative colitis we had intended to start as early as mid-year calendar 2020, a planned Phase 2 clinical trial with PL3994, an NPR-A agonist, in heart failure patients in collaboration with two major academic medical centers, and clinical trials planned to be conducted in the People's Republic of China and the Republic of Korea by our licensees for Vyleesi, Fosun and Kwangdong. Effects on our clinical trial programs include, but are not limited to:

delays or difficulties in enrolling patients in our clinical trials;

delays or difficulties in clinical site initiation, including difficulties in establishing appropriate and safe social distancing and other safeguards at clinical sites;

diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;

limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families, delays or difficulties in conducting site visits and other required travel, and the desire of employees to avoid contact with large groups of people; and

delays in receiving approval from local regulatory authorities to initiate or continue our planned clinical trials.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

# The COVID-19 coronavirus could adversely impact our business and revenues.

We receive a royalty on sales of Vyleesi by our licensees. AMAG is currently selling Vyleesi in the United States, and Fosun and Kwangdong have licenses to sell Vyleesi in China and Korea, respectively. We do not know the effect of the COVID-19 coronavirus on sales of Vyleesi in the United States, but it could have a negative impact on sales, which would adversely impact our royalty revenues. The COVID-19 coronavirus could adversely impact the time required to obtain regulatory approvals to sell Vyleesi in China and Korea, which would delay when we receive royalty income from sales in those countries.

# The announcement by AMAG of its intent to divest itself of its women's healthcare products, including Vyleesi, creates significant uncertainty regarding marketing, sales and distribution of Vyleesi in the United States.

On January 9, 2020, AMAG announced plans to divest Vyleesi and Intrarosa® (prasterone), both women's healthcare products. While AMAG indicated that it has received preliminary expressions of interest to acquire or sublicense rights to these products, there have been no public disclosures of any potential licensees of AMAG's rights to Vyleesi in North America. In 2017, we licensed all rights to commercialize Vyleesi in North America to AMAG, and following the U.S. Food and Drug Administration approval of Vyleesi in June 2019, AMAG launched Vyleesi nationally in September 2019 through select specialty pharmacies with its women's health sales force. Under the license agreement, AMAG has a contractual obligation to use commercially reasonable efforts to commercialize Vyleesi, and if AMAG materially breaches its obligations, we could have the right to terminate the license agreement and require AMAG to assign and transfer certain Vyleesi rights to Palatin. In the event AMAG assigns its Vyleesi license to a third party, the assignee must expressly agree to be bound by the license agreement between AMAG and Palatin.

If AMAG fails to assign or license rights to Vyleesi to a third party with the resources and capability to effectively market Vyleesi, we could experience significant delays or an inability to successfully commercialize Vyleesi. Even if AMAG assigns or licenses rights to Vyleesi to a third party with the resources and capability to effectively market Vyleesi, there may be significant delays in the successful commercialization of Vyleesi for HSDD in North America, and we may be unable to realize the potential value of the license agreement in a timely manner. If we obtain all rights to Vyleesi from AMAG, as a result of termination of the license agreement for breach or otherwise, we will need to contract for or establish sales and marketing, contract manufacturing, distribution, pharmacovigilance and related capabilities, which will be expensive and time consuming. If we are unable to establish adequate capabilities to make and sell Vyleesi, whether independently or with third parties, we may not be able to generate product revenue and our business would suffer.

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

As indicated in the table below, 22,658 shares were withheld during the three months ended March 31, 2020 at the direction of the employees as permitted under the 2011 Stock Incentive Plan in order to pay the minimum amount of tax liability owed by the employee from the vesting of those units:

				Total Number of Shares Purchased as Part of Publicly	Maximum Number of Shares that May Yet be Purchased Under
Fiscal Month Period	Total Number of Shares Purchased <sup>(1)</sup>	Aver	eighted age Price r Share	Announced Plans or Programs	Announced Plans or Programs
January 1, 2020 through Janurary 31, 2020	22,658	\$	0.69		-
February 1, 2020 through February 29, 2020	-		-	-	-
March 1, 2020 through March 31, 2020	<u> </u>		-	<u>-</u>	
Total	22,658	\$	0.69		

<sup>(1)</sup> Consists solely of 22,658 shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock units.

# 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.
<u>31.1</u>	Certification of Chief Executive Officer.	X			
<u>31.2</u>	Certification of Chief Financial Officer.	X			
<u>32.1</u>	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.	Χ			
32.2	Certification of principal financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Χ			
101.INS	XBRL Instance Document.	Χ			
101.SCH	XBRL Taxonomy Extension Schema Document.	Χ			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Χ			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Χ			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Х			
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# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

# Palatin Technologies, Inc.

(Registrant)

/s/ Carl Spana

Carl Spana, Ph.D. President and

Chief Executive Officer (Principal

Executive Officer)

/s/ Stephen T. Wills

Stephen T. Wills, CPA, MST

Executive Vice President, Chief Financial Officer and

Chief Operating Officer

(Principal Financial and Accounting Officer)

Date: May 11, 2020

Date: May 11, 2020