UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 - Q

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

For the quarterly period ended September 30, 2020

or

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

For the transition period from _____ to _____

Commission file number: 001-15543

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

Delaware	**95-4078884**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4B Cedar Brook Drive Cranbury, New Jersey	**08512**
(Address of principal executive offices)	(Zip Code)

(609) 495-2200

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to

be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (November 13, 2020): 229,901,307

PALATIN TECHNOLOGIES, INC.

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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 business, financial condition, and results of operations may be adversely affected by global health epidemics, including the novel strain of coronavirus ("COVID-19") pandemic and its resurgence of cases in the United States, such as, for example, increase in costs of and delays in conducting human clinical trials and the performance of our contractors and suppliers, and reduction in our productivity or the productivity of our contractors and suppliers;

our ability to successfully commercialize Vyleesi® (the trade name for bremelanotide) for the treatment of premenopausal women with hypoactive sexual desire disorder ("HSDD") in the United States, which may be adversely affected by delays or disruptions related to the ongoing COVID-19 pandemic;

our ability to manage the infrastructure to successfully manufacture, through contract manufacturers, Vyleesi, and to develop the infrastructure to successfully market and distribute Vyleesi in the United States;

our ability to meet post-marketing requirements of the U.S. Food and Drug Administration ("FDA") to conduct two additional studies and one additional clinical trial for Vyleesi;

our expectations regarding the potential market size and market acceptance for Vyleesi for HSDD in the United States and elsewhere in the world;

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:

- 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");

our expectations and the ability of our licensees to timely obtain approvals and successfully commercialize Vyleesi in countries other than the United States;

estimates of our expenses, future revenue, and capital requirements;

our ability to achieve profitability;

our ability to obtain additional financing on terms acceptable to us, or at all, including unavailability of funds or delays in receiving funds as a result of the ongoing COVID-19 pandemic;

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

- the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals;
- our expectations regarding the 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;
- the potential to achieve revenues from the sale of our product candidates;
- our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers, and other healthcare payers;
- our ability to maintain product liability insurance at a reasonable cost or in sufficient amounts, if at all;
- the performance of our management team, senior staff professionals, and third-party contractors and consultants;
- the retention of key management, employees, and third-party contractors;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology in the United States and throughout the world;
- our compliance with federal and state laws and regulations;
- the timing and costs associated with obtaining regulatory approval for our product candidates, including delays and additional costs related to the ongoing COVID-19 pandemic;
- 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® and Vyleesi® are registered trademarks of Palatin Technologies, Inc. Other trademarks referred to in this report are the property of their respective owners.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2020	June 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$86,587,455	$82,852,270
Accounts receivable	5,044,372	-
Inventories	5,792,595	-
Prepaid expenses and other current assets	2,360,001	738,216
Total current assets	99,784,423	83,590,486
Property and equipment, net	126,772	140,216
Right-of-use assets	1,190,410	1,266,132
Other assets	56,916	56,916
Total assets	$101,158,521	$85,053,750
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 971,308	$ 715,672
Accrued expenses	3,823,682	2,899,097
Short-term operating lease liabilities	282,275	312,784
Other current liabilities	7,575,000	-
Total current liabilities	12,652,265	3,927,553
Long-term operating lease liabilities	911,775	953,348
Other long-term liabilities	10,619,000	-
Total liabilities	24,183,040	4,880,901
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock of $0.01 par value – authorized 10,000,000 shares; shares issued and outstanding designated as follows:		
Series A Convertible: authorized 264,000 shares: issued and outstanding 4,030 shares as of September 30, 2020 and June 30, 2020	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 229,855,417 shares as of September 30, 2020 and 229,258,400 shares as of June 30, 2020	2,298,554	2,292,584
Additional paid-in capital	396,816,565	396,079,127
Accumulated deficit	(322,139,678)	(318,198,902)
Total stockholders' equity	76,975,481	80,172,849
Total liabilities and stockholders' equity	$101,158,521	$85,053,750

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

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

	Three Months Ended September 30,	
	2020	**2019**
REVENUES		
Product revenue, net	$ (288,560)	$ -
License and contract	-	97,379
	(288,560)	97,379
OPERATING EXPENSES		
Cost of products sold	25,200	-
Research and development	2,923,851	3,127,489
Selling, general and administrative	2,331,606	1,832,442
Gain on license termination agreement	(1,623,795)	-
Total operating expenses	3,656,862	4,959,931
Loss from operations	(3,945,422)	(4,862,552)
OTHER INCOME (EXPENSE)		
Investment income	12,135	370,654
Interest expense	(7,489)	(9,051)
Total other income, net	4,646	361,603
NET LOSS	$(3,940,776)	$(4,500,949)
Basic and diluted net loss per common share	$ (0.02)	$ (0.02)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	236,345,862	233,113,241

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

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

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance, June 30, 2020	4,030	$ 40	229,258,400	$ 2,292,584	$396,079,127	$(318,198,902)	$80,172,849
Stock-based compensation	-	-	743,112	7,431	813,743	-	821,174
Withholding taxes related to restricted stock units	-	-	(146,095)	(1,461)	(76,305)	-	(77,766)
Net loss	-	-	-	-	-	(3,940,776)	(3,940,776)
Balance, September 30, 2020	4,030	$ 40	229,855,417	$ 2,298,554	$396,816,565	$(322,139,678)	$76,975,481

	Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated 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	-	-	224,000	2,240	825,495	-	827,735
Sale of common stock , net of costs	-	-	657,894	6,579	573,151	-	579,730
Warrant repurchase	-	-	-	-	(1,333,497)	-	(1,333,497)
Net loss	-	-	-	-	-	(4,500,949)	(4,500,949)
Balance, September 30, 2019	4,030	$ 40	227,697,257	$ 2,276,973	$394,119,078	$(300,273,828)	$96,122,263

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

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

	Three Months Ended September 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(3,940,776)	$(4,500,949)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	13,444	18,253
Cash received in excess of gain on termination agreement	10,376,205	-
Non-cash interest expense	-	438
Decrease in right-of-use asset	75,722	72,113
Stock-based compensation	821,174	827,735
Changes in operating assets and liabilities:		
Accounts receivable	(744,372)	60,168,591
Prepaid expenses and other assets	(1,621,785)	39,436
Inventories	25,200	-
Accounts payable	255,636	(446,964)
Accrued expenses	(1,375,415)	(1,269,232)
Operating lease liabilities	(72,082)	(72,113)
Net cash provided by operating activities	3,812,951	54,837,308
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	-	(62,880)
Net cash used in investing activities	-	(62,880)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of withholding taxes related to restricted stock units	(77,766)	-
Payment on notes payable obligations	-	(832,851)
Warrant repurchases	-	(1,333,497)
Proceeds from the sale of common stock, net of costs	-	579,730
Net cash used in financing activities	(77,766)	(1,586,618)
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,735,185	53,187,810
CASH AND CASH EQUIVALENTS, beginning of period	82,852,270	43,510,422
CASH AND CASH EQUIVALENTS, end of period	$86,587,455	$96,698,232
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 7,489	$ 8,132

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

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

(1) ORGANIZATION

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

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

The Company's lead product, Vyleesi®, was approved by the U.S. Food and Drug Administration ("FDA") in June 2019 and was being marketed in North America by AMAG Pharmaceuticals, Inc. ("AMAG") for the treatment of hypoactive sexual desire disorder ("HSDD") in premenopausal women pursuant to a license agreement between them for Vyleesi for North America, which was entered into on January 8, 2017 (the "AMAG License Agreement"). As disclosed in Note 5, the AMAG License Agreement was terminated effective July 24, 2020, and the Company is now marketing Vyleesi in North America.

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 generally incurred negative cash flows from operations, and has expended, and expects to continue to expend, substantial funds to develop the capability to market and distribute Vyleesi in the United States and complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company had an accumulated deficit as of September 30, 2020 of $322,139,678 and a net loss for the three months ended September 30, 2020 of $3,940,776, and the Company anticipates incurring significant expenses in the future as a result of spending on developing marketing and distribution capabilities for Vyleesi in the United States and spending on its development programs and will require substantial additional financing or revenues to continue to fund its planned developmental activities. To achieve sustained profitability, if ever, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct successful preclinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach sustained profitability is highly uncertain, and the Company may never be able to achieve profitability on a sustained basis, if at all.

As of September 30, 2020, the Company's cash and cash equivalents were $86,587,455 and current liabilities were $12,652,265. Management intends to utilize existing capital resources for general corporate purposes and working capital, including establishing marketing and distribution capabilities for Vyleesi in the United States and 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 cash and cash equivalents as of September 30, 2020 will be sufficient to fund our current operating plans through at least December 2021. The Company will need additional funding to complete required clinical trials for its other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required applications to the FDA. If the Company is unable to obtain approval or otherwise advance in the FDA approval process, the Company's ability to sustain its operations could be materially adversely affected.

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 will receive a royalty on sales of Vyleesi by our licensees. We have licensed third parties to sell Vyleesi in China and Korea. 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, including the recent resurgence of cases in the United States, 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 2021 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, cash equivalents and accounts receivable. The Company's cash and cash equivalents are primarily invested in one money market account sponsored by a large financial institution. For the three months ended September 30, 2020, the Company recorded a gain of $1,623,795 related to the termination of the AMAG License Agreement. In connection with the termination agreement, the Company has a receivable balance due from AMAG of $4,300,000 as of September 30, 2020. For the three months ended September 30, 2019, the Company reported $97,379 in revenue related to the AMAG License Agreement.

(2) BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnote disclosures required to be presented for complete financial statements. In the opinion of management, these consolidated financial statements contain all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation. The results of operations for the three months ended September 30, 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, 2020, filed with the Securities and Exchange Commission ("SEC"), which includes consolidated financial statements as of June 30, 2020 and 2019 and for each of the fiscal years in the three-year period ended June 30, 2020.

(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 $86,396,008 and $82,406,697 in a money market account at September 30, 2020 and June 30, 2020, respectively.

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

Credit Risk – Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and accounts receivable. Total cash and cash equivalent balances have exceeded balances insured by the Federal Depository Insurance Company. Currently accounts receivable are due exclusively from AMAG.

Inventories – Inventory is stated at the lower of cost or net realizable value, with cost being determined on a first-in, first-out basis.

On a quarterly basis, the Company reviews inventory levels to determine whether any obsolete, expired, or excess inventory exists. If any inventory is expected to expire prior to being sold, has a cost basis in excess of its net realizable value, is in excess of expected sales requirements as determined by internal sales forecasts, or fails to meet commercial sale specifications, the inventory is written-down through a charge to cost of products sold. Once packaged, inventory has a shelf-life ranging from three to five years.

Property and Equipment – Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements and includes assets acquired under finance 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 finance 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 $2,466,289 and $2,452,845 as of September 30, 2020 and June 30, 2020, 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.

Leases - At lease inception, the Company determines whether an arrangement is or contains a lease. Operating leases are included in operating lease right-of-use ("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.

The Company has operating leases for office and laboratory space, which expire on June 30, 2025 and October 31, 2023, respectively. The Company also has operating leases for copier equipment that expire October 15, 2021 and phone equipment that expires on June 30, 2023.

Revenue Recognition – The Company principally sells Vyleesi to specialty pharmacies and payment is currently made within approximately 30 days. The specialty pharmacies subsequently resell the products to healthcare providers and patients. In addition to distribution agreements with customers, the Company enters into arrangements with healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

Revenue from product sales is recognized when control is transferred to the customer, which occurs at the point in time when the goods are shipped. In instances when the Company performs shipping and handling activities, these are considered fulfillment activities, and accordingly, the costs are accrued when the related revenue is recognized.

The Company records product revenues net of allowances for direct and indirect fees, discounts, estimated chargebacks and rebates. Product sales are also subject to return rights, which have not been significant to date.

Gross product sales were offset by product sales allowances for the three months ended September 30, 2020 as follows:

Gross product sales	$ 809,100
Provision for product sales allowances and accruals	(1,097,660)
Net sales	$ (288,560)

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 in the future and such sales-based royalties and milestone payments will be recognized in the same period earned.

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

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

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 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 product revenue and 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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 260, *Earnings per Share*.

For the three months ended September 30, 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 September 30, 2020 and 2019 was 38,526,609 and 37,497,717, respectively.

Included in the weighted average common shares used in computing basic and diluted net loss per common share are 6,444,353 and 5,978,150 vested restricted stock units that had not been issued as of September 30, 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 August 2020, the FASB issued Accounting Standards Update ("ASU") No. 2020-06, *Debt (Topic 470) and Derivatives and Hedging (Topic 815): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The amendments in this update address issues identified as a result of the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. The guidance is effective for public entities for fiscal years beginning after December 15, 2021, and for interim periods within those fiscal years, with early adoption permitted. The guidance is applicable to the Company beginning July 1, 2022. The Company is currently evaluating the potential effects of this guidance on its consolidated financial statements.

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.

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 was applicable to the Company beginning July 1, 2020. The adoption of this standard did not have a material impact on the Company's 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, 2023 with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

(5) AGREEMENTS 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 three months ended September 30, 2019, license and contract revenue included additional billings for AMAG related Vyleesi costs of $97,379.

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.

Effective July 24, 2020, the Company entered into a termination agreement (the "Termination Agreement") with AMAG terminating the AMAG License Agreement. Under the terms of the Termination Agreement, the Company has regained all development and commercialization rights for Vyleesi in the Territory. AMAG made a $12,000,000 payment to the Company at closing of the Termination Agreement and will make a $4,300,000 payment to the Company on March 31, 2021. The Company recorded a liability related to estimated losses on inventory purchase commitments of $18,194,000 as well as accrued expenses for an inventory production run obligation assumed of $2,300,000. As a result, the Company recorded a net gain for the Termination Agreement of $1,623,795. The Company has assumed all Vyleesi manufacturing agreements, and AMAG has transferred information, data, and assets related exclusively to Vyleesi to the Company, including existing inventory with a fair value of $5,817,795.

Under the Termination Agreement, AMAG is providing certain transitional services to the Company for a period to ensure continued patient access to Vyleesi during the transition back to the Company. The Company is reimbursing AMAG for the agreed upon costs of the transition services.

(6) MANUFACTURING SUPPLY AGREEMENTS FOR VYLEESI:

Pursuant to the Termination Agreement, the Company assumed Vyleesi manufacturing contracts with Catalent Belgium S.A. ("Catalent"), a subsidiary of Catalent Pharma Solutions, Inc., to manufacture drug product and prefilled syringes and assemble prefilled syringes into an auto-injector device (the "Catalent Agreement"), Ypsomed AG ("Ypsomed"), to manufacture the auto-injector device (the "Ypsomed Agreement"), and Lonza Ltd. ("Lonza"), to manufacture the active pharmaceutical ingredient peptide (the "Lonza Agreement").

On September 29, 2020, the Company and Catalent entered into an agreement to terminate the Catalent Agreement (the "Catalent Termination Agreement") in consideration for a one-time payment of six million euros (€6,000,000) which was paid in October 2020 and accrued as part of the estimated losses on inventory purchase commitments assumed as part of the Termination Agreement as discussed in note 5.

The Company and Catalent then entered into a new Vyleesi manufacturing agreement (the "New Catalent Agreement") which includes reduced minimum annual purchase requirements (see note 13) as compared to the original Catalent Agreement and modification of other financial terms. The New Catalent Agreement provides that Catalent will provide manufacturing and supply services to Palatin related to production of Vyleesi, including that Catalent will supply specified minimums of Palatin's requirements for Vyleesi during the term of the New Catalent Agreement through August 21, 2025, unless earlier terminated in accordance with the terms of the New Catalent Agreement. The initial term of the New Catalent Agreement will be automatically extended for one 24-month period unless either party notifies the other of its desire to terminate as of the end of the initial term. The New Catalent Agreement also includes customary terms and conditions relating to forecasting and minimum commitments, ordering, delivery, inspection and acceptance, and termination, among other matters.

The term of the Lonza Agreement is through December 31, 2022. There are specified minimum purchase requirements under the Lonza Agreement, and under specified circumstances, termination fees may be payable upon termination of the Lonza Agreement by the Company (see note 13).

The initial term of the Ypsomed Agreement is through December 31, 2025, with automatic renewal for successive one-year periods unless either party terminates the Ypsomed Agreement by ten months' written notice prior to the expiration of the Ypsomed Agreement or any automatic renewal period. There are specified minimum purchase requirements under the Ypsomed Agreement, and under specified circumstances, termination fees may be payable upon termination of the Ypsomed Agreement by the Company (see note 13).

(7) 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.

(8) 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. 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.

(9) PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	September 30, 2020	June 30, 2020
Clinical / regulatory costs	$ 28,346	$ 43,625
Insurance premiums	78,654	84,741
Vyleesi contractual advances	1,500,000	-
Other	753,001	609,850
	$ 2,360,001	$ 738,216

(10) FAIR VALUE MEASUREMENTS

The fair value of cash equivalents is classified using a hierarchy prioritized based on inputs. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on management's own assumptions used to measure assets and liabilities at fair value. A financial asset's or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets carried at fair value:

	Carrying Value	Quoted prices in active markets (Level 1)	Other quoted/observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2020:				
Money Market Account	$86,396,008	$86,396,008	$ -	$ -
June 30, 2020:				
Money Market Account	$82,406,697	$82,406,697	$ -	$ -

(11) ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2020	June 30, 2020
Clinical / regulatory costs	$ 701,733	$ 1,722,729

Other research related expenses	511,803	586,185
Professional services	79,913	217,662
Inventory purchases	2,300,000	-
Other	230,233	372,521
	$ 3,823,682	$ 2,899,097

(12) NOTES PAYABLE:

On July 2, 2015, the Company closed on a $10,000,000 venture loan 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 August 1, 2019. The lenders also received five-year immediately exercisable Series G warrants to purchase 549,450 shares of the Company's common stock exercisable at an exercise price of $0.91 per share. The Company recorded a debt discount of $305,196 equal to the fair value of these warrants at issuance, which were amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and was included in additional paid-in capital on the Company's balance sheet. In addition, a final incremental payment of $500,000 was due on August 1, 2019. This final incremental payment was accreted to interest expense over the term of the related debt and was included in other current liabilities on the consolidated balance sheet. The Company incurred $146,115 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the three months ended September 30, 2019, the loan matured, and on July 31, 2019, the Company made the final incremental payment of $500,000.

(13) COMMITMENTS AND CONTINGENCIES

As a result of the Termination Agreement and subsequent activity, the Company has certain supply agreements with manufacturers and suppliers, including the New Catalent Agreement, Lonza Agreement and Ypsomed Agreement. The Company is required to make certain payments for the manufacture and supply of Vyleesi. The following table summarizes the contractual obligations under the Catalent Termination Agreement, New Catalent Agreement, Lonza Agreement and Ypsomed Agreement as of September 30, 2020:

	Total	Current	1-3 Years	4-5 Years
Inventory purchase commitments	$18,667,000	$ 8,048,000	$ 8,226,000	$ 2,393,000

As of September 30, 2020, the Company has $7,575,000 and $10,619,000 accrued within other current and long-term liabilities, respectively, in the consolidated balance sheet related to estimated losses for firm commitment contractual obligations under these agreements. Losses on these firm commitment contractual obligations are recognized based upon the terms of the respective agreement and similar factors considered for the write-down of inventory, including expected sales requirements as determined by internal sales forecasts.

The Company is subject to numerous contingencies, such as product liability, arising in the ordinary course of business. Loss contingency provisions are recorded for probable losses when management is able to reasonably estimate the loss. Any outcome upon settlement that deviates from the Company's best estimate may result in additional expense or in a reduction in expense in a future accounting period. The Company records legal expenses associated with such contingencies as incurred.

(14) STOCKHOLDERS' EQUITY

Financing Transactions – On June 21, 2019, the Company entered into an equity distribution agreement with Canaccord Genuity LLC ("Canaccord") (the "2019 Equity Distribution Agreement"), pursuant to which the Company may, from time to time, sell shares of the Company's common stock at market prices by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The 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.

Proceeds raised under the 2019 Equity Distribution Agreement are as follows:

	Three Months Ended September 30, 2020		Three Months Ended September 30, 2019		Cumulative from inception	
	Shares	Proceeds	Shares	Proceeds	Shares	Proceeds

Gross proceeds	-	$ -	657,894	$ 664,670	9,460,509	$12,330,242
Fees	-	-	-	(19,940)	-	(369,908)
Expenses	-	-	-	(65,000)	-	(90,000)
Net proceeds	**-**	**$ -**	**657,894**	**$679,730**	**9,460,509**	**$11,870,334**

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

During the three months ended September 30, 2019, the Company entered into several warrant termination agreements to repurchase and cancel the following previously issued Series H and Series J warrants for the following aggregate buyback prices:

	Warrants	Buyback price
Series H Warrants	474,045	$ 186,773
Series J Warrants	2,866,809	1,146,724
	3,340,854	$ 1,333,497

Stock Options – For the three months ended September 30, 2020 and 2019, the Company recorded stock-based compensation related to stock options of $481,822 and $344,160, respectively

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, 2020	19,902,450	$ 0.76	7.4	$ 380,514
Granted	154,500	0.58		
Forfeited	-			
Exercised	-			
Expired	(14,000)	1.70		
Outstanding - September 30, 2020	20,042,950	$ 0.76	7.2	$ 269,535
Exercisable at September 30, 2020	10,790,450	$ 0.78	5.6	$ 211,601
Expected to vest at September 30, 2020	9,252,500	$ 0.74	9.0	$ 57,934

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 1,994,500 and 188,084 performance-based options granted in June 2020 to executive officers and employees, respectively. The performance-based options vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials and licensing of Vyleesi in additional countries or regions.

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

Restricted Stock Units – For the three months ended September 30, 2020 and 2019, the Company recorded stock-based compensation related to restricted stock units of $339,352 and $483,575, respectively.

A summary of restricted stock unit activity is as follows:

	RSUs
Outstanding at July 1, 2020	12,965,570
Granted	-
Forfeited	-
Vested	(743,112)
Outstanding at September 30,2020	12,222,458

Included in outstanding restricted stock units in the table above 6,444,353 vested shares that have not been issued as of September 30, 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 48 months, 48 months, and 12 months, respectively.

In June 2020, the Company granted 1,203,500 performance-based restricted stock units to its executive officers and 113,484 performance-based restricted stock units to other employees which vest during a performance period ending June 24, 2024. 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 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, 2020.

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, 2020, 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

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, 2020, have not changed during the three months ended September 30, 2020 with the exception of product revenue, inventory and purchase commitment liabilities. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported carrying value of inventory and purchase commitment liabilities. Actual results may differ from these estimates under different assumptions or conditions. In addition to the policies related to the carrying value of inventory and purchase commitment liabilities, 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 January 2020, our North American licensee for Vyleesi® (bremelanotide injection), AMAG Pharmaceuticals, Inc. ("AMAG"), announced that it had completed a strategic review of its product portfolio and business strategy, and was pursuing options to divest its female health products, including Vyleesi. On July 27, 2020, Palatin and AMAG announced that they had mutually terminated the license agreement for Vyleesi effective July 24, 2020, and that we were assuming responsibility for manufacturing, marketing and distribution of Vyleesi in North America, including the United States.

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 FDA on June 21, 2019, and since July 24, 2020 we have been marketing Vyleesi in the United States. Prior to July 24, 2020, the product was marketed in North America by AMAG pursuant to a license agreement that was terminated on that date. Vyleesi, a melanocortin receptor agonist, is an "as needed" therapy used in anticipation of sexual activity and self-administered by premenopausal women with HSDD in the thigh or abdomen via a single-use subcutaneous auto-injector. The most common adverse events are

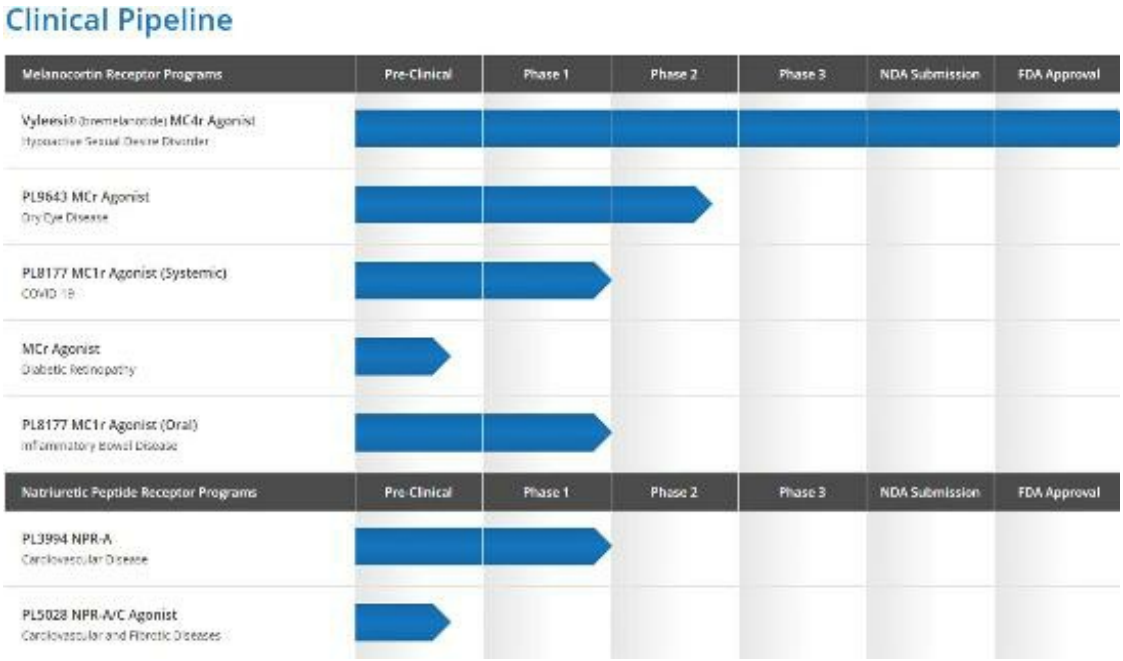
nausea, flushing, injection site reactions, headache, and vomiting. Vyleesi is contraindicated in women with uncontrolled hypertension or known cardiovascular disease. In addition, the Vyleesi label includes precautions that it may cause (i) small, transient increases in blood pressure with a corresponding decrease in heart rate; (ii) focal hyperpigmentation (darkening of the skin on certain parts of the body), including the face, gums (gingiva) and breasts; and (iii) nausea.

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

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

Pipeline Overview

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



Our Strategy

Key elements of our business strategy include:

- Maximizing revenue from Vyleesi by marketing Vyleesi in the United States, supporting our existing licensees for China and South Korea, and seeking licensees for Vyleesi in the United States and additional regions;
- 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, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained in it or connected to it are not incorporated into this Quarterly Report on Form 10-Q. The reference to our website is an inactive textual reference only.

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

Results of Operations

Three months Ended September 30, 2020 Compared to the Three months Ended September 30, 2019:

Revenues – For the three months ended September 30, 2020 we recognized $(288,560) in product revenue, net of allowances as the result of our regaining all North American development and commercialization rights to Vyleesi in July 2020 (see notes 5 and 6 of our accompanying consolidated financial statements). For the three months ended September 30, 2020, we recognized no contract and license revenue compared to $97,379 for the three months ended September 30, 2019 pursuant to our prior license agreement with AMAG.

Research and Development – Research and development expenses were $2,923,851 and $3,127,489 for the three months ended September 30, 2020 and 2019, respectively. The decrease for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, is related to the overall decreases in program spending offset by higher compensation related expenses.

Research and development expenses related to our Vyleesi, PL3994, PL8177, MC1r, MC4r and other preclinical programs were $1,872,305 and $2,297,542 for the three months ended September 30, 2020 and 2019, respectively. The decrease is the result of timing of activities in research and development programs.

The amounts of project spending above exclude general research and development spending, which was $1,051,546 and $829,947 for the three months ended September 30, 2020 and 2019, respectively. The increase in general research and development spending for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 is primarily attributable to an increase in compensation related expenses.

Cumulative spending from inception to September 30, 2020 was approximately $311,600,000 on our Vyleesi program and approximately $157,400,000 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, 2020, 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.

Cost of Products Sold – Cost of products sold was $25,200 for the three months ended September 30, 2020.

Selling, General and Administrative – Selling, general and administrative expenses, which consist mainly of compensation and related costs, were $2,331,606 and $1,832,442 for the three months ended September 30, 2020 and 2019, respectively. The increase in selling, general and administrative expenses for the three months ended September 30, 2020 is primarily attributable to selling expenses related to Vyleesi and an increase in compensation related expenses.

Gain on License Termination Agreement - For the three months ended September 30, 2020, we recorded a gain of $1,623,795 as a result of the Vyleesi Termination Agreement. (see note 5 of the accompanying consolidated financial statements).

Other Income (Expense) – Total other income (expense), net was $4,646 and $361,603 for the three months ended September 30, 2020 and 2019, respectively. For the three months ended September 30, 2020 and 2019, we recognized $12,135 and $370,654, respectively, of investment income offset by $7,489 and $9,051, respectively, of interest expense. The decrease in investment income is a result of lower interest rates as a result of the COVID-19 pandemic.

Liquidity and Capital Resources

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

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

- the development and testing of products in animals and humans;
- product approval or clearance;
- regulatory compliance;
- good manufacturing practices ("GMP") compliance;
- intellectual property rights;
- product introduction;
- marketing, sales, and competition; and
- obtaining sufficient capital.

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

During the three months ended September 30, 2020, net cash provided by operating activities was $3,812,951 compared to $54,837,308 for the three months ended September 2019. The difference in cash provided by operations for the nine months ended September 30, 2020 compared to the three months ended September, 2019 was primarily related to the timing of the receipt of payments related to our license agreement with AMAG, including payments related to the FDA's approval of Vylessi.

During the three months ended September 30, 2020, net cash used in investing activities was zero compared to $62,880 for the three months ended September 30, 2019 for the purchase of equipment.

During the three months ended September 30, 2020, net cash used in financing activities was $77,766, which consisted of payment of withholding taxes related to restricted stock units. During the three months ended September 30, 2019, net cash used in financing activities was $1,586,618, which consisted of payment on a note payable obligation of $832,851 and repurchase and cancellation of outstanding warrants of $1,333,497 offset by proceeds from the sale of common stock of $579,730 in our "at-the-market" offering program.

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 develop the capability to market and distribute Vylessi and to complete our planned product development efforts. Continued operations are dependent upon our ability to generate future income from sales of Vylessi in the United States and from existing licenses, including royalties and milestones, to complete equity or debt financing activities and to enter into additional licensing or collaboration arrangements. As of September 30, 2020, our cash and cash equivalents were $86,587,455 and our current liabilities were $12,652,265.

We intend to utilize existing capital resources for general corporate purposes and working capital, establishing marketing and distribution capabilities for Vyleesi in the United States, 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 December 2021. We will need additional funding to complete required clinical trials for our other 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 the operations, financial position, and the results of operations and cash flows during fiscal year 2021 and beyond.

We expect to incur significant expenses as we continue to develop marketing and distribution capability for Vylessi in the United States and continue to develop our natriuretic peptide and MC1r product candidates. 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.

Contractual Obligations

We have entered into various contractual obligations and commercial commitments. The following table summarizes our most significant contractual obligations as of September 30,2020:

	Total	Current	1 - 3 Years	4 - 5 Years
Inventory purchase commitments	$18,667,000	$ 8,048,000	$ 8,226,000	$ 2,393,000
Operating leases	1,190,410	282,275	474,839	433,296
	$19,857,410	$ 8,330,275	$ 8,700,839	$ 2,826,296

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required to be provided by smaller reporting companies.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 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.

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, 2020.

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

As disclosed in the table below, 146,095 shares were withheld during the three months ended September 30, 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 employees from the vesting of those units:

Fiscal Month Period	Total Number of Shares Purchased (1)	Weighted Average Price per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet be Purchased Under Announced Plans or Programs
July 1, 2020 through July 31, 2020	-	$ -	-	-
August 1, 2020 through August 31, 2020	-	-	-	-
September 1, 2020 through September 30, 2020	146,095	0.53	-	-
Total	146,095	$ 0.53	-	-

(1) Consists solely of 146,095 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.
10.1	Termination and Release Agreement dated September 29, 2020, by and between Catalent Belgium S.A. and Palatin Technologies, Inc.	X			
10.2†	Commercial Supply Agreement dated September 29, 2020, by and between Catalent Belgium S.A. and Palatin Technologies, Inc.	X			
31.1	Certification of Chief Executive Officer.	X			
31.2	Certification of Chief Financial Officer.	X			
32.1	Certification of principal executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2	Certification of principal financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	XBRL Instance Document.	X			
101.SCH	XBRL Taxonomy Extension Schema Document.	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X			

† Portions of the exhibit are omitted pursuant to Regulation S-K Item 601(b)(10). Palatin agrees to furnish to the U.S. Securities and Exchange Commission a copy of any omitted schedule and/or exhibit upon request. The confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

Palatin Technologies, Inc.
(Registrant)

/s/ Carl Spana

Date: November 16, 2020

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

/s/ Stephen T. Wills

Date: November 16, 2020

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