PALATIN TECHNOLOGIES INC
Form 10-Q
November 09, 2018

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, 2018

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)

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	(Do not check if a smaller reporting company)	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 8, 2018): 203,063,429.

PALATIN TECHNOLOGIES, INC.
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Special Note Regarding Forward-Looking Statements

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

Statements in this Quarterly Report on Form 10-Q, as well as oral statements that may be made by us or by our officers, directors, or employees acting on our behalf, that are not historical facts constitute “forward-looking statements,” which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”). The forward-looking statements in this Quarterly Report on Form 10-Q do not constitute guarantees of future performance. Investors are cautioned that statements that are not strictly historical facts contained in this Quarterly Report on Form 10-Q, including, without limitation, the following are forward looking statements:

estimates of our expenses, future revenue and capital requirements;

our ability to achieve and maintain profitability;

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

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

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

the timing or likelihood of regulatory filings and approvals;

our expectations regarding completion of required clinical trials and studies and validation of methods and controls used to manufacture Vyleesi™ (the trade name for bremelanotide) for the treatment of premenopausal women with hypoactive sexual desire disorder (“HSDD”), which is a type of female sexual dysfunction (“FSD”);

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

our expectation regarding performance of our exclusive licensees of Vyleesi, including;

o
AMAG Pharmaceuticals, Inc. (“AMAG”) for North America,

o
Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (“Fosun”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., for the territories of the People’s Republic of China, Taiwan, Hong Kong S.A.R.

and Macau S.A.R. (collectively, the “Chinese Territories”), and

o
Kwangdong Pharmaceutical Co., Ltd. (“Kwangdong”) for the Republic of Korea (“Korea”);

the potential for commercialization of Vyleesi for HSDD in North America by AMAG and other product candidates, if approved, by us;

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

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

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

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

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

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

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

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

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

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

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

our compliance with federal and state laws and regulations;

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

the impact of fluctuations in foreign exchange rates;

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

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

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

Such forward-looking statements involve risks, uncertainties and other factors that could cause our actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. Our future operating results are subject to risks and uncertainties and are dependent upon many factors, including, without limitation, the risks identified under Part II, Item IA “Risk Factors” and elsewhere in this Quarterly Report, our Annual Report on Form 10-K for the year ended June 30, 2018 and in our other reports filed with the U.S. Securities and Exchange Commission (the “SEC”). Except as required by law, we do not intend, and undertake no obligation, to publicly update forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

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

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

PALATIN TECHNOLOGIES, INC.

and Subsidiary

Consolidated Balance Sheets

(unaudited)

	September 30, 2018	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$32,619,064	$38,000,171
Accounts receivable	104,189	-
Prepaid expenses and other current assets	420,639	513,688
Total current assets	33,143,892	38,513,859
Property and equipment, net	149,990	164,035
Other assets	338,916	338,916
Total assets	$33,632,798	$39,016,810
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,165,151	$2,223,693
Accrued expenses	2,020,333	2,103,021
Notes payable, net of discount	4,305,242	5,948,763
Other current liabilities	969,179	487,488
Total current liabilities	8,459,905	10,762,965
Notes payable, net of discount	-	332,898
Deferred revenue	-	500,000
Other non-current liabilities	-	456,038

Total liabilities	8,459,905	12,051,901
Stockholders' equity:		
Preferred stock of $0.01 par value – authorized 10,000,000 shares:		
Series A Convertible: issued and outstanding 4,030 shares as of September 30, 2018 and June 30, 2018	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 203,032,129 shares as of September 30, 2018 and 200,554,205 shares as of June 30, 2018	2,030,321	2,005,542
Additional paid-in capital	360,370,494	357,005,233
Accumulated deficit	(337,227,962)	(332,045,906)
Total stockholders' equity	25,172,893	26,964,909
Total liabilities and stockholders' equity	$33,632,798	$39,016,810

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,	
	2018	2017
REVENUES:		
License and contract	$34,505	$26,941,508
OPERATING EXPENSES:		
Research and development	3,622,691	14,163,097
General and administrative	2,040,582	1,544,575
Total operating expenses	5,663,273	15,707,672
(Loss) income from operations	(5,628,768)	11,233,836
OTHER INCOME (EXPENSE):		
Investment income	153,583	51,726
Interest expense	(206,871)	(456,677)
Total other expense, net	(53,288)	(404,951)
(Loss) income before income taxes	(5,682,056)	10,828,885
Income tax expense	-	(225,255)
NET (LOSS) INCOME	$(5,682,056)	$10,603,630
Basic net (loss) income per common share	$(0.03)	$0.05

Diluted net (loss) income per common share	$(0.03)	$0.05
Weighted average number of common shares outstanding used in computing basic net (loss) income per common share	205,009,278	197,112,400
Weighted average number of common shares outstanding used in computing diluted net (loss) income per common share	205,009,278	201,360,736

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

PALATIN TECHNOLOGIES, INC.

and Subsidiary

Consolidated Statements of Comprehensive (Loss) Income

(unaudited)

	Three Months Ended September 30,	
	2018	2017
Net (loss) income	$(5,682,056)	$10,603,630
Other comprehensive income :		
Unrealized gain on available-for-sale investments	-	437
Total comprehensive (loss) income	$(5,682,056)	$10,604,067

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

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

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance, June 30, 2018	4,030	$40	200,554,205	$2,005,542	$357,005,233	$-	$(332,045,906)	$26,964,909
Cumulative effect of accounting change	-	-	-	-	-	-	500,000	500,000
Stock-based compensation	-	-	319,817	3,198	1,230,387	-	-	1,233,585
Sale of common stock , net of costs	-	-	2,225,145	22,251	2,200,196	-	-	2,222,447
Withholding taxes related to restricted stock units	-	-	(67,038)	(670)	(65,322)	-	-	(65,992)
Net loss	-	-	-	-	-	-	(5,682,056)	(5,682,056)
Balance, September 30, 2018	4,030	$40	203,032,129	$2,030,321	$360,370,494	$-	$(337,227,962)	$25,172,893

	Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total

Balance, June 30, 2017	4,030	$40	160,515,361	$1,605,153	$349,974,538	$(590)	$(356,743,785)	$(5,164,644)
Cumulative effect of accounting change	-	-	-	-	4,835	-	(4,835)	-
Stock-based compensation	-	-	75,071	751	421,120	-	-	421,871
Warrant exercises	-	-	23,802,575	238,026	(123,642)	-	-	114,384
Unrealized gains on investments	-	-#	-	-	-	437	-	437
Net income	-	-	-	-	-	-	10,603,630	10,603,630
Balance, September 30, 2017	4,030	$40	184,393,007	$1,843,930	$350,276,851	$(153)	$(346,144,990)	$5,975,678

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

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PALATIN TECHNOLOGIES, INC.

and Subsidiary

Consolidated Statements of Cash Flows

(unaudited)

	Three Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	$(5,682,056)	$10,603,630
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	14,045	14,616
Non-cash interest expense	23,581	56,182
Stock-based compensation	1,233,585	421,871
Changes in operating assets and liabilities:		
Accounts receivable	(104,189)	5,727,100
Prepaid expenses and other assets	93,049	71,236
Accounts payable	(1,058,542)	482,271
Accrued expenses	(82,688)	(1,112,295)
Deferred revenue	-	(14,890,191)
Other non-current liabilities	25,653	60,435
Net cash (used in) provided by operating activities	(5,537,562)	1,434,855
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	-	(9,500)
Net cash used in investing activities	-	(9,500)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on capital lease obligations	-	(7,110)
Payment of withholding taxes related to restricted stock units	(65,992)	(24,380)
Payment on notes payable obligations	(2,000,000)	(2,000,000)

Proceeds from the exercise of common stock warrants	-	114,384
Proceeds from the sale of common stock, net of costs	2,222,447	-
Net cash provided by (used in) financing activities	156,455	(1,917,106)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(5,381,107)	(491,751)
CASH AND CASH EQUIVALENTS, beginning of period	38,000,171	40,200,324
CASH AND CASH EQUIVALENTS, end of period	$32,619,064	$39,708,573
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$157,636	$340,365
Cash paid for income taxes	-	500,000

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

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

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

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

Business Risk and Liquidity – Since inception, the Company has incurred negative cash flows from operations, and has expended, and expects to continue to expend, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company had an accumulated deficit as of September 30, 2018 of $337,227,962 and a net loss for the three months ended September 30, 2018 of $5,682,056, and the Company anticipates incurring significant expenses in the future as a result of spending on its development programs and will require substantial additional financing or revenues to continue to fund its planned developmental activities. To achieve sustained profitability, if ever, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct successful preclinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach sustained profitability is highly uncertain, and the Company may never be able to achieve profitability on a sustained basis, if at all.

As of September 30, 2018, the Company's cash and cash equivalents, were $32,619,064 and current liabilities were $8,459,905. The Company intends to utilize existing capital resources for general corporate purposes and working capital, including, preclinical and clinical development of our MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

Management believes that the Company's existing capital resources, together with proceeds received from sales of common stock in the Company's "at-the-market" program (if any), will be adequate to fund the Company's planned operations through at least December 31, 2019. The Company will need additional funding to complete required clinical trials for its other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required applications to the FDA. If the Company is unable to obtain approval or otherwise advance in the FDA approval process, the Company's ability to sustain its operations would be materially adversely affected.

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.

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

Concentrations – Concentrations in the Company's assets and operations subject it to certain related risks. Financial instruments that subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents and 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, 2018, the Company reported $34,505 in license and contract revenue related to a license agreement with AMAG for Vyleesi for North America ("AMAG License Agreement") (Note 5). For the three months ended September 30, 2017, the Company reported $21,941,508 in contract revenue related to the AMAG License Agreement and $5,000,000 in contract revenue related to Fosun (the "Fosun License Agreement") (Note 6)

(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, 2018 may not necessarily be indicative of the results of operations expected for the full year.

The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2018, filed with the SEC, which includes consolidated financial statements as of June 30, 2018 and 2017 and for each of the fiscal years in the three-year period ended June 30, 2018.

(3)
SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

Cash and Cash Equivalents – Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a purchased maturity of less than three months. Cash equivalents consist of $32,431,016 and $37,808,099 in a money market account at September 30, 2018 and June 30, 2018, respectively.

Fair Value of Financial Instruments – The Company's financial instruments consist primarily of cash equivalents, accounts receivable, accounts payable and notes 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. Management believes that the carrying amount of its notes payable approximates fair value based on terms of the notes.

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

Property and Equipment – Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements and includes assets acquired under capital leases. Property and equipment are recorded at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets, generally five years for laboratory and computer equipment, seven years for office furniture and equipment and the lesser of the term of the lease or the useful life for leasehold improvements. Amortization of assets acquired under capital leases is included in depreciation expense. Maintenance and repairs are expensed as incurred while expenditures that extend the useful life of an asset are capitalized. Accumulated depreciation and amortization was $2,352,603 and $2,338,558 as of September 30, 2018 and June 30, 2018, respectively.

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

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

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

On July 1, 2018, the Company adopted ASC Topic 606 using the modified retrospective approach, a practical expedient permitted under ASC Topic 606, and applied this approach only to contracts that were not completed as of July 1, 2018. The Company calculated a one-time cumulative transition adjustment of $500,000 which was recorded on July 1, 2018 to the opening balance of accumulated deficit related to its license agreement with Kwangdong (the "Kwangdong License Agreement") as the Company determined a significant revenue reversal would not occur in a future period. The one-time adjustment consisted of the recognition of $500,000 of deferred revenue.

Revenue recognition for periods prior to July 1, 2018

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

the delivered item had value to the customer on a stand-alone basis; and

if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered item was considered probable and substantially in control of the vendor.

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

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

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

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

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

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

Revenue recognition for periods commencing July 1, 2018

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

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

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

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

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

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

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

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PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

The impact of adoption of ASC Topic 606 on the Company's consolidated balance sheet as of September 30, 2018 is as follows:

PALATIN TECHNOLOGIES, INC.

and Subsidiary

Consolidated Balance Sheets

(unaudited)

	Impact of change in accounting policies		
	As reported September 30, 2018	Adjustments	As reported without adoption of ASC Topic 606
ASSETS			
Current assets:			
Cash and cash equivalents	$32,619,064	$-	$32,619,064
Accounts receivable	104,189	-	104,189
Prepaid expenses and other current assets	420,639	-	420,639
Total current assets	33,143,892	-	33,143,892
			-
Property and equipment, net	149,990	-	149,990
Other assets	338,916	-	338,916
Total assets	$33,632,798	$-	$33,632,798
			-
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			

Accounts payable	$1,165,151	$-	$1,165,151
Accrued expenses	2,020,333	-	2,020,333
Notes payable, net of discount	4,305,242	-	4,305,242
Other current liabilities	969,179	-	969,179
Total current liabilities	8,459,905	-	8,459,905
			-
Notes payable, net of discount	-	-	-
Deferred revenue	-	500,000	500,000
Other non-current liabilities	-	-	-
Total liabilities	8,459,905	500,000	8,959,905
Stockholders' equity:			
Preferred stock	40	-	40
Common stock	2,030,321	-	2,030,321
Additional paid-in capital	360,370,494	-	360,370,494
Accumulated deficit	(337,227,962)	(500,000)	(337,727,962)
Total stockholders' equity	25,172,893	(500,000)	24,672,893
Total liabilities and stockholders' equity	$33,632,798	$-	$33,632,798

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

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

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

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

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

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

The Company continues to maintain a full valuation allowance against its net deferred tax assets. Other provisions enacted include a new provision designed to tax low-taxed income of foreign subsidiaries (i.e., "GILTI") and a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P") from controlled foreign corporations ("CFC"). The Company does not have any foreign subsidiaries, and thus these provisions do not apply.

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During the year ended June 30, 2018, the Company recorded income tax expense of $82,500, which consisted of $500,000 that was withheld in accordance with tax withholding requirements in the Chinese Territories related to the Fosun License Agreement (Note 6) and $82,500, which was withheld in accordance with tax withholding requirements in Korea related to the Kwangdong License Agreement (Note 7). The total income tax expense related to withholding requirements of $582,500 was offset by an income tax benefit of $500,000, which resulted from the 2017 Tax Act, under which AMT credits became refundable, and therefore a $500,000 benefit related to the release of a valuation allowance against an AMT credit was recorded during the three months ended December 2017. The Company's June 30, 2017 tax return was filed during the three months ended March 31, 2018 and the Company did not incur an AMT liability. As a result, as of September 30, 2018 and June 30, 2018, the Company has a current income tax receivable of $218,000 and a long-term income tax receivable of $282,000 from estimated AMT that can be refunded in the future.

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

The following table is a reconciliation of net (loss) income and the shares used in calculating basic and diluted net (loss) income per common share for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,	
	2018	2017
Net (loss) income	$(5,682,056)	$10,603,630
Denominator:		
Weighted average common shares - Basic	205,009,278	197,112,400
Effect of dilutive shares:		
Common stock equivalents arising from stock options, warrants and conversion of preferred stock	-	1,413,791
Restriced stock units	-	2,834,545
Weighted average common shares - Diluted	205,009,278	201,360,736
Net (loss) income per common share:		

Basic	$(0.03)	$0.05
Diluted	$(0.03)	$0.05

As of September 30, 2017, common shares issuable upon the exercise of outstanding options and warrants, excluding outstanding warrants exercisable for nominal consideration, and the vesting of restricted stock units amounted in an aggregate of 11,116,667 shares being excluded from the weighted average number of common shares used in computing diluted net income per common share because they were anti-dilutive during the period or the minimum performance requirements or market conditions had not been met. For the three months ended September 30, 2018, no additional common shares were added to the computation of diluted EPS because to do so would have been anti-dilutive. The potential number of common shares excluded from diluted EPS during the three months ended September 30, 2018 was 44,454,308.

Included in the weighted average common shares used in computing basic and diluted net income (loss) per common share are 3,347,999 and 1,729,250 vested RSUs that have not been issued as of September 30, 2018 and 2017, respectively, due to a provision in the RSU agreements to delay delivery.

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(4)
NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending June 30, 2019 and interim periods within that annual period. Early adoption is permitted. The Company adopted this guidance during the three months ended September 30, 2018. 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, 2020. Early adoption will be available on July 1, 2019. The Company is currently evaluating the effect that ASU No. 2016-13 will have on its consolidated financial statements and related disclosures.

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

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance relates to the recognition and measurement of financial assets and liabilities. The new guidance makes targeted improvements to GAAP impacting equity investments (other than those accounted for under the equity method or consolidated), financial liabilities accounted for under the fair value election, and presentation and disclosure requirements for financial instruments, among other changes. The Company adopted this guidance during the three months ended September 30, 2018. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

(5)
AGREEMENT WITH AMAG

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

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

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The Company determined there was no stand-alone value for the license, and that the license and the reimbursable direct out-of-pocket expenses, pursuant to the terms of the License Agreement, represented a combined unit of accounting which totaled $85,000,000. The Company recognized revenue of the combined unit of accounting over the arrangement using the input-based proportional method as the Company completed its development obligations. For the three months ended September 30, 2017, the Company recognized $21,941,508 as license and contract revenue. During the three months ended September 30, 2018, license and contract revenue included additional billings for AMAG related Vyleesi costs of $34,505.

In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, the Company will be eligible to receive from AMAG (i) up to $60,000,000 upon FDA approval of Vyleesi, and (ii) up to $300,000,000 in sales milestone payments based on achievement of certain annual net sales for all Products in the Territory.

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

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

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

(6)
AGREEMENT WITH FOSUN:

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

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(7)
AGREEMENT WITH KWANGDONG:

On November 21, 2017, the Company entered into the Kwangdong License Agreement for exclusive rights to commercialize Vyleesi in Korea.

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

(8)
PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	September 30, 2018	June 30, 2018
Clinical study costs	$62,453	$145,994
Insurance premiums	30,986	42,605
Other	327,200	325,089
	$420,639	$513,688

(9)
FAIR VALUE MEASUREMENTS

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

The following table provides the assets carried at fair value:

	Carrying Value	Quoted prices in active markets(Level 1)	Other quoted/observable inputs (Level 2)	Significant unobservable inputs(Level 3)
September 30, 2018:				
Money market account	$32,431,016	$32,431,016	$-	$-
June 30, 2018:				
Money market account	$37,808,099	$37,808,099	$-	$-

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(10)
ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2018	June 30, 2018
Clinical study costs	$673,376	$983,410
Other research related expenses	662,466	590,236
Professional services	66,062	297,731
Severance	555,184	115,362
Other	63,245	116,282
	$2,020,333	$2,103,021

(11)
NOTES PAYABLE:

Notes payable consist of the following:

	September 30, 2018	June 30, 2018
Notes payable under venture loan	$4,333,334	$6,333,334
Unamortized related debt discount	(18,496)	(33,535)
Unamortized debt issuance costs	(9,596)	(18,138)
Notes payable	4,305,242	6,281,661
Less: current portion	4,305,242	5,948,763
Long-term portion	$-	$332,898

On December 23, 2014, the Company closed on a $10,000,000 venture loan which was led by Horizon Technology Finance Corporation (“Horizon”). The debt facility is a four-year senior secured term loan that bears interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50%, and provides for interest-only payments for the first eighteen months followed by monthly payments of principal of $333,333 plus accrued interest through January 1, 2019. The lenders also received five-year immediately exercisable Series D 2014 warrants to purchase 666,666 shares of common stock exercisable at an exercise price of $0.75 per share. The Company recorded a debt discount of $267,820 equal to the fair value of these warrants at issuance, which is being amortized to interest expense over the term of the related debt. This debt discount is offset against the note payable balance and included in additional paid-in capital on the Company’s balance sheet at September 30, 2018 and June 30, 2018. In addition, a final incremental payment of $500,000 is due on January 1, 2019, or upon early repayment of the loan. This final incremental payment is being accreted to interest expense over the term of the related debt and is included in other current liabilities on the consolidated balance sheet as of September 30, 2018. The Company incurred $209,367 of costs in connection with the loan. These costs were capitalized as deferred financing costs and are offset against the note payable balance. These debt issuance costs are being amortized to interest expense over the term of the related debt.

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On July 2, 2015, the Company closed on a $10,000,000 venture loan led by Horizon. The debt facility is a four-year senior secured term loan that bears interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50% and provides for interest-only payments for the first eighteen months followed by monthly payments of principal of $333,333 plus accrued interest through August 1, 2019. The lenders also received five-year immediately exercisable Series G warrants to purchase 549,450 shares of the Company's common stock exercisable at an exercise price of $0.91 per share. The Company has recorded a debt discount of $305,196 equal to the fair value of these warrants at issuance, which is being amortized to interest expense over the term of the related debt. This debt discount is offset against the note payable balance and is included in additional paid-in capital on the Company's balance sheet at September 30, 2018 and June 30, 2018. In addition, a final incremental payment of $500,000 is due on August 1, 2019, or upon early repayment of the loan. This final incremental payment is being accreted to interest expense over the term of the related debt and is included in other current liabilities on the consolidated balance sheet as of September 30, 2018. The Company incurred $146,115 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and are offset against the note payable balance. These debt issuance costs are being amortized to interest expense over the term of the related debt.

The Company's obligations under the 2015 amended and restated loan agreement, which includes both the 2014 venture loan and the 2015 venture loan, are secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company also has agreed to specified limitations on pledging or otherwise encumbering its intellectual property assets. The 2015 amended and restated loan agreement includes customary affirmative and restrictive covenants, but does not include any covenants to attain or maintain specified financial metrics. The loan agreement includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan agreement. As of September 30, 2018, the Company was in compliance with all of its loan covenants.

(12)
STOCKHOLDERS' EQUITY

Financing Transactions – On April 20, 2018, the Company entered into an equity distribution agreement (the "Equity Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of the Company's common stock at market prices by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company will pay Canaccord 3.0% of the gross proceeds as a commission. Between July 1, 2018 and September 30, 2018, a total of 2,225,145 shares of common stock were sold through Canaccord under the Equity Distribution Agreement for net proceeds of $2,222,447 after payment of commission fees of $68,735. The Company has no obligation to sell any shares under the Equity Distribution Agreement and may at any time suspend solicitation and offers under the Equity Distribution Agreement.

Stock Purchase Warrants – During the three months ended September 30, 2017, the Company issued 12,364,219 shares of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of $0.01 per share and received $114,384 and issued 11,438,356 shares of common stock pursuant to the exercise of warrants at an exercise price of $0.01 per share.

Stock Options – For the three months ended September 30, 2018 and 2017, the Company recorded stock-based compensation related to stock options of $323,703 and $159,874, respectively.

In July 2018, the terms of certain options were modified to accelerate vesting and extend the option life. As a result the Company recorded additional stock-based compensation of $109,004 during the three months ended September 30, 2018. There were no such modifications during the three months ended September 30, 2017.

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A summary of stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Outstanding - July 1, 2018	12,775,462	0.76	7.7	
Granted	-	-		
Forfeited	(133,851)	0.53		
Expired	(129,150)	1.77		
Outstanding - September 30, 2018	12,512,461	0.75	7.5	3,320,734
Exercisable at September 30, 2018	6,263,674	$0.77	6.0	$1,659,518
Expected to vest at September 30, 2018	6,248,787	$0.74	9.0	$1,661,216

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 125,000 performance-based options granted in December 2017 to executive officers and employees, respectively, which vest during a performance period ending on December 31, 2020, if and upon either i) as to 100% of the target number of shares upon achievement of a closing price for the Company's common stock equal to or greater than $1.50 per share for 20 consecutive trading days, which is considered a market condition; or ii) as to thirty percent (30%) of the target number of shares, upon the acceptance for filing by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is considered a performance condition; iii) as to fifty percent (50%) of the target number of shares, upon the approval by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is also considered a performance condition; iv) as to twenty percent (20%) of the target number of shares, upon entry into a licensing agreement during the performance period for the commercialization of Vyleesi for FSD in selected countries, which is also considered a performance condition. The fair value of these options was $602,760. The Company is amortizing the fair value over the derived service period of 1.1 years or upon the attainment of the performance condition. Pursuant to the FDA acceptance of the NDA filing of Vyleesi, 30% of the target number of options vested in June 2018.

Restricted Stock Units – For the three months ended September 30, 2018 and 2017, the Company recorded stock-based compensation related to restricted stock units of $800,878 and $261,997, respectively.

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A summary of restricted stock unit activity is as follows:

	Number of RSU's
Outstanding at July 1, 2018	9,323,876
Granted	-
Forfeited	(178,851)
Vested	(319,817)
Outstanding at September 30, 2018	8,825,208

Included in outstanding RSUs in the table above are 3,347,999 vested shares that have not been issued as of September 30, 2018 due to a provision in the RSU agreements to delay delivery.

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

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

(13)
SUBSEQUENT EVENTS

Between October 1, 2018 and November 8, 2018, a total of 31,300 shares of the Company's common stock were sold through Canaccord under the Equity Distribution Agreement for net proceeds of $30,361 after payment of commission fees of $939.

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

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes to the consolidated financial statements filed as part of this report and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended June 30, 2018.

Critical Accounting Policies and Estimates

Except for the adoption of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC Topic 606"), our significant accounting policies, which are described in the notes to our consolidated financial statements included in this report and in our Annual Report on Form 10-K for the year ended June 30, 2018, have not changed during the three months ended September 30, 2018. We believe that our accou