SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 8-K

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act Of 1934

Date of Report (Date of earliest event reported): February 12, 2019

Palatin Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-15543**	**95-4078884**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS employer identification number)

4B Cedar Brook Drive, Cranbury, NJ	**08512**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:
(609) 495-2200

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by checkmark 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. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 12, 2019, we issued a press release including results for our second quarter ended December 31, 2019 and announcing a teleconference and webcast to be held February 12, 2019 at 11:00 a.m. Eastern time, which will include a discussion on results of operations in greater detail and an update on corporate developments. We have attached a copy of the press release as an exhibit to this report.

The information in this Item 2.02 and the corresponding information in the attached Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in this Item 2.02 and the corresponding information in the attached Exhibit 99.1 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated February 12, 2019

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 hereunto duly authorized.

PALATIN TECHNOLOGIES, INC.

Date: February 12, 2019

By: /s/ Stephen T. Wills
Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

99.1	Press Release dated February 12, 2019

Palatin Technologies, Inc. Reports Second Fiscal Quarter 2019 Results and Provides Corporate Update

Teleconference and Webcast to be held on February 12, 2019

CRANBURY, NJ – February 12, 2019 – Palatin Technologies, Inc. (NYSE American: PTN), a specialized biopharmaceutical company developing first-in-class medicines based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems for the treatment of diseases with significant unmet medical need and commercial potential, today announced results for its second quarter ended December 31, 2018.

Recent Highlights and Program Updates

Female Sexual Dysfunction / Vyleesi™ (bremelanotide)

- Vyleesi, the trade name for bremelanotide - Under development for Hypoactive Sexual Desire Disorder ("HSDD"):

  The Prescription Drug User Fee Act ("PDUFA") date for completion of FDA review of the Vyleesi New Drug Application ("NDA") was extended three months to June 23, 2019.

  The U.S. Food and Drug Administration ("FDA") requested a Phase 1 study in premenopausal volunteers assessing short term daily use of Vyleesi. This study is ongoing and is being conducted by Palatin and AMAG Pharmaceuticals, our exclusive licensee for North America.

    Study results are anticipated to be submitted to the FDA prior to the updated PDUFA date.

  Palatin is in discussions with potential collaboration partners for certain regions outside of the licensed territories of North America, China and South Korea.

Anti-Inflammatory / Autoimmune Programs

- Melanocortin receptor 1 and 1/5 ("MC1r", "MC1/5r") agonists under development for the treatment of inflammatory and autoimmune diseases such as dry eye, uveitis, diabetic retinopathy and inflammatory bowel diseases:

  PL-8177, a selective MC1r peptide agonist:

    Completed subcutaneous dosing of human subjects in a Phase 1 single and multiple ascending dose clinical safety study, with no safety or tolerability concerns noted in a press release dated November 8, 2018.

    A separate clinical study with oral dosing in human subjects was started during the quarter ended December 31, 2018, with data expected in the first quarter of calendar year 2019.

    Program is under internal evaluation for orphan designations.

  PL-8331 and PL-9643, dual MC1r and MC5r peptide agonists:

    Continuing with preclinical Investigational New Drug ("IND") enabling activities.

    Program is under internal evaluation for orphan designations.

Natriuretic Peptide Receptor ("NPR") System Program

- We have designed and are developing potential NPR candidate drugs that are selective for one or more different natriuretic peptide receptors, including natriuretic peptide receptor-A ("NPR-A"), natriuretic peptide receptor B ("NPR-B"), and natriuretic peptide receptor C ("NPR-C"):

  PL-3994, an NPR-A agonist that has potential utility in treatment of a number of cardiovascular diseases, including genetic and orphan diseases resulting from a deficiency of endogenous active NPR-A.

  Academic collaborations with several institutions ongoing.

  PL-5028, a dual NPR-A and NPR-C agonist in development for cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis.

  Academic collaborations with several institutions ongoing.

Genetic Obesity Program

- Melanocortin receptor 4 ("MC4r") peptide PL-8905 and orally-active small molecule PL-9610 under development for the treatment of rare genetic metabolic and obesity disorders:

  Program is under internal evaluation for orphan designations.

Corporate

- Decreased debt and related liabilities from $7.2 million at June 30, 2018 to $2.8 million at December 31, 2018.

Second Quarter Fiscal 2019 Financial Results

Palatin reported a net loss of $(5.0) million, or $(0.02) per basic and diluted share, for the quarter ended December 31, 2018, compared to net income of $3.0 million, or $0.02 per basic and $0.01 per diluted share, for the same period in 2017.

The difference in financial results between the three months ended December 31, 2018 and 2017 was primarily attributable to the recognition of $10.6 million in license and contract revenue during the 2017 period pursuant to our license agreement with AMAG.

Revenue

There were no revenues recorded in the quarter ended December 31, 2018.

For the quarter ended December 31, 2017, 100% of the revenue Palatin recognized was related to our license agreement with AMAG.

Operating Expenses

Total operating expenses for the quarter ended December 31, 2018 were $5.1 million compared to $7.7 million for the comparable quarter of 2017. The decrease in operating expenses was mainly attributable to the completion of the Vyleesi Phase 3 clinical trial program and ancillary studies necessary to file the NDA in HSDD in March 2018.

Other Income/Expense

Total other income, net was $7,871 for the quarter ended December 31, 2018 compared to total other expenses, net $(0.3) million for the quarter ended December 31, 2017. The difference is related primarily to the decrease in interest expense related to Palatin's venture debt.

Income Tax

There was no income tax expense, or benefit, recorded in the quarter ended December 31, 2018.

Pursuant to the license agreements with Fosun and Kwangdong, $500,000 and $82,500, respectively, was withheld in accordance with tax withholding requirements in China and the Republic of Korea, respectively, and was recorded as an expense during the fiscal year ended June 30, 2018. For the quarter ended December 31, 2017, Palatin recorded $100,880 in income tax expense related to those withholding amounts utilizing an estimated effective annual income tax rate applied to income for the quarter and the remaining balance of $256,365 was included in prepaid expenses and other current assets at December 31, 2017. Any potential credit to be received by Palatin on its United States tax returns is currently offset by Palatin's valuation allowance. The $100,880 of income tax expense was offset by a $500,000 tax benefit that Palatin recorded in the quarter ended December 31, 2017 related to the release of a valuation allowance against Palatin's federal alternative minimum tax credit as a result of the Tax Cuts and Jobs Act signed in December 2017. Accordingly, $500,000 was included in other long-term assets at December 31, 2017.

Cash Position

Palatin's cash, and cash equivalents were $24.7 million as of December 31, 2018, compared to cash and cash equivalents of $38.0 million at June 30, 2018. Current liabilities were $4.5 million as of December 31, 2018, compared to $10.8 million as of June 30, 2018.

Palatin believes that existing capital resources will be sufficient to fund our planned operations through at least March 31, 2020.

Palatin Drug Discovery Programs

In the conference call and webcast, management will update and discuss next steps in Palatin's portfolio of drug development programs. These include Palatin's MC1r and MC1/5r agonist peptides for treatment of anti-inflammatory and autoimmune indications, MC4r peptide and small molecule agonists for the treatment of genetic obesity indications and natriuretic peptide receptor agonist compounds for treatment of cardiovascular and pulmonary indications.

Conference Call / Webcast

Palatin will host a conference call and webcast on February 12, 2019 at 11:00 a.m. Eastern Time to discuss the quarter ended December 31, 2018 results of operations in greater detail and provide an update on corporate developments. Individuals interested in listening to the conference call live can dial 1-877-260-1479 (US/Canada) or 1-334-323-0522 (international), conference ID 4414047. The webcast and replay can be accessed by logging on to the "Investor/Webcasts" section of Palatin's website at http://www.palatin.com. A telephone and webcast replay will be available approximately one hour after the completion of the call. To access the telephone replay, dial 1-888-203-1112 (US/Canada) or 1-719-457-0820 (international), passcode 4414047. The webcast and telephone replay will be available through February 19, 2019.

About Palatin Technologies, Inc.

Palatin Technologies, Inc. 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, with targeted, receptor-specific product candidates for the treatment of diseases with significant unmet medical need and commercial potential. Palatin's strategy is to develop products and then form marketing collaborations with industry leaders in order to maximize their commercial potential. For additional information regarding Palatin, please visit Palatin's website at www.Palatin.com.

Forward-looking Statements

Statements in this press release that are not historical facts, including statements about future expectations of Palatin Technologies, Inc., such as statements about clinical trial results, potential actions by regulatory agencies including the FDA, regulatory plans, development programs, proposed indications for product candidates and market potential for product candidates, are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and as that term is defined in the Private Securities Litigation Reform Act of 1995. Palatin intends that such forward-looking statements be subject to the safe harbors created thereby. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause Palatin's actual results to be materially different from its historical results or from any results expressed or implied by such forward-looking statements. Palatin's actual results may differ materially from those discussed in the forward-looking statements for reasons including, but not limited to, results of clinical trials, regulatory actions by the FDA and the need for regulatory approvals, Palatin's ability to fund development of its technology and establish and successfully complete clinical trials, the length of time and cost required to complete clinical trials and submit applications for regulatory approvals, products developed by competing pharmaceutical, biopharmaceutical and biotechnology companies, commercial acceptance of Palatin's products, and other factors discussed in Palatin's periodic filings with the Securities and Exchange Commission. Palatin is not responsible for updating for events that occur after the date of this press release.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
REVENUES:				
License and contract	$ -	$ 10,612,153	$ 34,505	$ 37,553,661
OPERATING EXPENSES:				
Research and development	2,961,656	6,045,884	6,584,347	20,208,981
General and administrative	2,088,565	1,625,189	4,129,147	3,169,764
Total operating expenses	5,050,221	7,671,073	10,713,494	23,378,745
(Loss) income from operations	(5,050,221)	2,941,080	(10,678,989)	14,174,916
OTHER INCOME (EXPENSE):				
Investment income	100,169	81,356	253,752	133,082
Interest expense	(92,298)	(391,363)	(299,169)	(848,040)
Total other income (expense), net	7,871	(310,007)	(45,417)	(714,958)
(Loss) income before income taxes	(5,042,350)	2,631,073	(10,724,406)	13,459,958
Income tax benefit	-	399,120	-	173,865
NET (LOSS) INCOME	$ (5,042,350)	$ 3,030,193	$ (10,724,406)	$ 13,633,823
Basic net (loss) income per common share	$ (0.02)	$ 0.02	$ (0.05)	$ 0.07
Diluted net (loss) income per common share	$ (0.02)	$ 0.01	$ (0.05)	$ 0.07
Weighted average number of common shares outstanding used in computing basic net (loss) income per common share	206,487,984	197,238,056	205,724,321	197,175,316
Weighted average number of common shares outstanding used in computing diluted net (loss) income per common share	206,487,984	202,711,616	205,724,321	200,430,824

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

	December 31, 2018	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,658,024	$ 38,000,171
Accounts receivable	-	-
Prepaid expenses and other current assets	535,147	513,688
Total current assets	25,193,171	38,513,859
Property and equipment, net	136,153	164,035
Other assets	338,916	338,916
Total assets	$ 25,668,240	$ 39,016,810
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 619,900	$ 2,223,693
Accrued expenses	1,101,045	2,103,021
Notes payable, net of discount	2,321,123	5,948,763
Other current liabilities	486,474	487,488
Total current liabilities	4,528,542	10,762,965
Notes payable, net of discount	-	332,898
Deferred revenue	-	500,000
Other non-current liabilities	-	456,038
Total liabilities	4,528,542	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 December 31, 2018 and June 30, 2018	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 203,063,429 shares as of December 31, 2018 and 200,554,205 shares as of June 30, 2018	2,030,634	2,005,542
Additional paid-in capital	361,379,336	357,005,233
Accumulated deficit	(342,270,312)	(332,045,906)
Total stockholders' equity	21,139,698	26,964,909
Total liabilities and stockholders' equity	$ 25,668,240	$ 39,016,810