SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 8-K

Date Filed: 2018-09-13

Corporate Issuer CIK: 911216

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): September 13, 2018

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**

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))

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 September 13, 2018, we issued a press release including results for our fourth quarter and fiscal year ended June 30, 2018 and announcing a teleconference and webcast to be held September 13, 2018 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 September 13, 2018

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: September 13, 2018

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 September 13, 2018

Palatin Technologies, Inc. Reports Fourth Quarter and Fiscal Year 2018 Results

Vyleesi™ New Tradename for Bremelanotide

PDUFA Target Action Date of March 23, 2019 for Vyleesi

Teleconference and Webcast to be held on September 13, 2018

CRANBURY, NJ – September 13, 2018 – 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 fourth quarter and fiscal year ended June 30, 2018.

"The last year has been very productive for Palatin, most notably the acceptance of the Vyleesi™ (bremelanotide) NDA by the FDA," said Carl Spana, Ph.D., CEO and President of Palatin. "Going forward, the first quarter of calendar year 2019 could bring FDA approval for Vylessi – a significant milestone and major inflection point for Palatin, its employees, its shareholders, and most importantly, the thousands of premenopausal women seeking treatment for HSDD in the U.S."

2018 Highlights and Recent Events

Vyleesi (bremelanotide)

- **Vyleesi™**, the trade name for bremelanotide - Under development for Hypoactive Sexual Desire Disorder ("HSDD"):
  - In June 2018, our exclusive North American Licensee for Vyleesi, AMAG Pharmaceuticals, Inc. (NASDAQ: AMAG) ("AMAG"), was notified by the U.S. Food and Drug Administration ("FDA") of acceptance for the filing of the New Drug Application ("NDA") on Vyleesi, with an FDA PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA review of the NDA of March 23, 2019.
    - FDA's acceptance of the NDA triggered a $20 million milestone payment to Palatin, less expenses paid by AMAG.
  - Palatin is entitled to receive up to $60 million upon regulatory approval by the FDA.
    - If approved, Vyleesi would become the first and only on-demand pharmacologic option indicated for the treatment of HSDD in premenopausal women in the U.S.

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- Entered into a collaboration and license agreement with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd in September 2017 for exclusive rights to develop and commercialize Vyleesi in the territories of mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R.
  - Received $4,500,000 in October 2017, consisting of an upfront payment of $5,000,000 less $500,000, which was withheld in accordance with tax withholding requirements in China.
- Entered into a license agreement with Kwangdong Pharmaceutical Co., Ltd. ("Kwangdong") in November 2017 for exclusive rights to develop and commercialize Vyleesi in the Republic of Korea.
  - 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 the Republic of Korea.

PL-8177 / PL-8331

- **Melanocortin Receptor 1 (MC1r) Agonists** under development for the treatment of inflammatory and autoimmune diseases such as dry eye, uveitis, diabetic retinopathy and inflammatory bowel diseases:
  - Completed subcutaneous dosing of human subjects with PL-8177 in a Phase 1 single and multiple ascending dose clinical safety study, with data expected in the fourth quarter of calendar 2018.
  - May 2018 – Presented positive preclinical data on PL-8331 at TIDES: Oligonucleotide and Peptide Therapeutics 2018 Meeting.
  - April 2018 – Presented preclinical oral formulation data on PL-8177, an investigational MC1r agonist for Inflammatory Bowel Diseases at the 2018 Keystone Symposia on "The Resolution of Inflammation in Health and Disease."

Corporate

- Decreased debt from $14.8 million at June 30, 2017 to $7.2 million at June 30, 2018.
- Added to the Russell 3000® Index in June 2018.
- Grew the company's intellectual property portfolio with several filings and issuances during the year.

Fourth Quarter and Fiscal 2018 Financial Results

Palatin reported net income of $11.8 million, or $0.06 per basic and diluted share, for the fourth quarter ended June 30, 2018, compared to net income of $13.3 million, or $0.07 per basic and diluted share, for the same period in 2017.

The difference between the three months ended June 30, 2018 and 2017 was primarily attributable to the recognition of contract revenue pursuant to our license agreement with AMAG of $20.6 million for the quarter ended June 30, 2018 compared to $33.9 million in 2017.

For the fiscal year ended June 30, 2018, Palatin reported net income of $24.7 million, or $0.12 per basic and diluted share compared to a net loss of $(13.3) million, or $(0.07) per basic and diluted share for the year ended June 30, 2017.

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The difference in net income for the year ended June 30, 2018, and the net loss for the year ended June 30, 2017, was primarily attributable to the recognition of $67.1 million in license and contract revenue for the year ended June 30, 2018 compared to $44.7 million for the year ended June 30, 2017, and secondarily to a $14.1 million decrease in operating expenses to $41.2 million for the year ended June 30, 2018 compared to $55.3 million for the year ended June 30, 2017.

Revenue

For the quarter and year ended June 30, 2018, Palatin recognized $20.6 million and $62.1 million, respectively, in contract revenue related to our license agreement with AMAG and an additional $5 million in license revenue for the year ended June 30, 2018 related to our license agreement with Fosun.

For the quarter and year ended June 30, 2017, Palatin recognized $33.9 million and $44.7 million, respectively, in contract revenue related to our license agreement with AMAG.

Operating Expenses

Total operating expenses for the quarter ended June 30, 2018 were $8.3 million compared to $19.6 million for the comparable quarter of 2017. For the year ended June 30, 2018, Palatin incurred $41.2 million of operating expenses, compared to $55.3 million for the year ended June 30, 2017.

The decrease in operating expenses was mainly attributable to the completion of Phase 3 clinical trials and less other development of Vyleesi for HSDD.

Other Income/Expense

Total other expense, net, was $0.2 million for the quarter ended June 30, 2018, compared to $0.5 million for the quarter ended June 30, 2017. For the year ended June 30, 2018, total other expense, net, was $1.1 million, compared to $2.3 million for the year ended June 30, 2017. Total other expense, net for both fiscal years ended June 30, 2018 and June 30, 2017 consisted mainly of interest expense related to venture debt.

Income Tax

Income tax expense was $0.3 and $0.1 million, respectively, for the quarter and year ended June 30, 2018 compared to $0.5 million in alternative minimum tax for the quarter and year ended June 30, 2017.

Income tax expense for the year ended June 30, 2018 relates to $0.6 million in tax withholding requirements related to our Fosun and Kwangdong license agreements that was recorded as an expense during the fiscal year ended June 30, 2018 offset by a tax benefit of $0.5 million 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, $0.5 million is included in other long-term assets at June 30, 2018.

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Cash Position

Palatin's cash and cash equivalents were $38.0 million and no accounts receivable at June 30, 2018, compared to cash, cash equivalents and investments of $40.5 million, and accounts receivable of $15.1 million at June 30, 2017. Current liabilities were $10.8 million as of June 30, 2018, compared to $19.9 million, net of deferred revenue of $35.1 million, as of June 30, 2017.

Palatin believes that existing capital resources will be sufficient to fund our planned operations through at least September 30, 2019.

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 melanocortin receptor1 and receptor-5 agonist peptides for treatment of inflammatory indications and natriuretic peptide receptor agonist compounds for treatment of cardiovascular and pulmonary indications.

Conference Call / Webcast

Palatin will host a conference call and audio webcast on September 13, 2018 at 11:00 a.m. Eastern Time to discuss the results of operations in greater detail and provide an update on corporate developments. Individuals interested in listening to the conference call live can dial 1-855-719-5012 (U.S./Canada) or 1-334-323-0522 (international), conference ID 5577225. The audio 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 (U.S./Canada) or 1-719-457-0820 (international), passcode 5577225. The webcast and telephone replay will be available through September 20, 2018.

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.

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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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(Financial Statement Data Follows)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Operations

	Year Ended June 30,		
	2018	**2017**	**2016**
REVENUES			
License and contract	$ 67,134,758	$ 44,723,827	$ -
OPERATING EXPENSES			
Research and development	32,566,217	45,683,174	43,071,051
General and administrative	8,641,976	9,610,147	6,179,084
Total operating expenses	41,208,193	55,293,321	49,250,135
Income (loss) from operations	25,926,565	(10,569,494)	(49,250,135)
OTHER INCOME (EXPENSE)			
Investment income	310,663	26,270	50,226
Interest expense	(1,452,014)	(2,288,309)	(2,513,027)
Total other expense, net	(1,141,351)	(2,262,039)	(2,462,801)
Income (loss) before income taxes	24,785,214	(12,831,533)	(51,712,936)
Income tax expense	(82,500)	(500,000)	-
NET INCOME (LOSS)	$ 24,702,714	$ (13,331,533)	$ (51,712,936)
Basic net income (loss) per common share	$ 0.12	$ (0.07)	$ (0.33)
Diluted net income (loss) income per common share	$ 0.12	$ (0.07)	$ (0.33)
Weighted average number of common shares outstanding used in computing basic net income (loss) per common share	198,101,060	184,087,719	156,553,534
Weighted average number of common shares outstanding used in computing diluted income (loss) income per common share	207,007,558	184,087,719	156,553,534

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Balance Sheets

	June 30, 2018	June 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,000,171	$ 40,200,324
Available-for-sale investments	-	249,837
Accounts receivable	-	15,116,822
Prepaid expenses and other current assets	513,688	1,011,221
Total current assets	38,513,859	56,578,204
Property and equipment, net	164,035	198,153
Other assets	338,916	56,916
Total assets	$ 39,016,810	$ 56,833,273
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 2,223,693	$ 1,551,367
Accrued expenses	2,103,021	10,521,098
Notes payable, net of discount	5,948,763	7,824,935
Capital lease obligations	-	14,324
Deferred revenue	-	35,050,572
Other current liabilities	487,488	-
Total current liabilities	10,762,965	54,962,296
Notes payable, net of discount	332,898	6,281,660
Deferred revenue	500,000	-
Other non-current liabilities	456,038	753,961
Total liabilities	12,051,901	61,997,917
Stockholders' equity (deficiency):		
Preferred stock of $0.01 par value – authorized 10,000,000 shares:		
Series A Convertible: issued and outstanding 4,030 shares as of June 30, 2018 and June 30, 2017	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares;		
issued and outstanding 200,554,205 shares as of June 30, 2018 and 160,515,361 as of June 30, 2017	2,005,542	1,605,153
Additional paid-in capital	357,005,233	349,974,538
Accumulated other comprehensive loss	-	(590)
Accumulated deficit	(332,045,906)	(356,743,785)
Total stockholders' equity (deficiency)	26,964,909	(5,164,644)
Total liabilities and stockholders' equity (deficiency)	$ 39,016,810	$ 56,833,273