SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 8-K

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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 28, 2020**

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))

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

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

Indicate by check mark whether the registrant 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 September 28, 2020, we issued a press release including results for our fourth quarter and fiscal year ended June 30, 2020 and announcing a teleconference and webcast to be held September 28, 2020 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 28, 2020

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 28, 2020

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 28, 2020

Palatin Technologies, Inc. Announces Fourth Quarter and Fiscal Year 2020 Financial Results and Provides a Business Update

- *$82.9 Million in Cash and Cash Equivalents at June 30, 2020*
- *Mutual Termination of License Agreement with AMAG Pharmaceuticals for Vyleesi® in July 2020 Resulted in Palatin Receiving $12 Million from AMAG Plus $4.3 Million Due March 31, 2021*
- *Phase 2 Study Data of PL9643 for the Treatment of Dry Eye Disease Expected in Fourth Calendar Quarter of 2020*
- *Teleconference and Webcast to be held on September 28, 2020*

CRANBURY, NJ – September 28, 2020 – 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, today announced financial results for its fourth quarter and fiscal year ended June 30, 2020.

Fourth Quarter and Fiscal Year 2020 Financial Highlights

- Net loss for the fourth quarter ended June 30, 2020 was $(7.3) million, or $(0.03) per basic and diluted share, compared to net income of $52.2 million, or $0.25 per basic and $0.23 per diluted share for the comparable quarter of 2019;
- Net loss for the year ended June 30, 2020 was $(22.4) million, or $(0.10) per basic and diluted share, compared to net income of $35.8 million, or $0.17 per basic and $0.16 per diluted share for the year ended June 30, 2019;
- The difference between the quarter and year ended June 30, 2020 compared to the quarter and year ended June 30, 2019 was due to the recognition of license and contract revenue pursuant to our license agreement with AMAG of $60.3 million for the quarter and year ended June 30, 2019;
- As of June 30, 2020, the Company had $82.9 million in cash and cash equivalents, compared to $43.5 million as of June 30, 2019, and no debt.

Recent Business Highlights and Updates

- In July 2020 mutually terminated the January 2017 license agreement granting AMAG Pharmaceuticals ("AMAG") exclusive North American rights to market Vyleesi® (bremelanotide), the first and only on demand treatment for premenopausal women suffering from acquired, generalized, hypoactive sexual desire disorder (HSDD), a condition affecting one in ten premenopausal women;
- Completed enrollment of a Phase 2 clinical study with PL9643 for the treatment of dry eye disease (DED). Final patient and topline data readout is targeted for the fourth calendar quarter of 2020;
- A Phase 2 proof-of-concept clinical study with an oral formulation of PL8177 in ulcerative colitis patients is targeted to start in the first half of calendar year 2021.

-More-

"We are pleased to have completed enrollment last month in our PL9643 Phase 2 clinical study in subjects with dry eye disease. Data readout is targeted for the fourth calendar quarter of 2020. We believe that, if approved, PL9643's potentially quick onset to efficacy and favorable tolerability and safety profile may provide a treatment option to the millions of individuals suffering from DED," stated Carl Spana, Ph.D., President and CEO of Palatin.

"We believe that Vyleesi is an important treatment for the millions of premenopausal women suffering from HSDD. Our goal with the Vyleesi program is to demonstrate value in the marketplace by increasing patient demand and access. Our objective is to re-license the U.S. rights to a committed women's healthcare company. Having taken steps to ensure no disruption for patient access to Vyleesi, we are working to expand awareness of the condition and treatment in a highly-targeted and informed manner, enhance and stream-line patient access, and increase insurance coverage."

Dr. Spana further commented, "Our strong cash position of $83 million at June 30, 2020 and no debt, coupled with the $12 million received in July 2020 from AMAG, plus an additional $4.3 million due from AMAG March 31, 2021, provides us the financial resources to significantly advance our Anti-Inflammatory and Autoimmune programs, and make complimentary targeted investments to our Vyleesi program."

"The entire Palatin team thanks healthcare workers across the nation for their selfless efforts in the treatment and care of COVID-19 patients. I would also like to thank all of our employees for their dedication and commitment to ensure the advancement of our development programs and clinical trial patient support," continued Spana. "Although Palatin has experienced limited adverse impact on operations from the pandemic, we are cognizant there may be further disruptions to business activity based on a resurgence of the virus and have taken steps to be as prepared as possible for this potential outcome."

Programs Overview

Hypoactive Sexual Desire Disorder (HSDD) / Vyleesi® (bremelanotide injection)

In July 2020, Palatin announced the mutual termination of its License Agreement with AMAG for Vyleesi. Under the terms of the termination agreement, Palatin regained all North American development and commercialization rights for Vyleesi. AMAG made a $12.0 million payment to Palatin at closing and will make a $4.3 million payment to Palatin on March 31, 2021. Palatin assumed all Vyleesi manufacturing agreements, and AMAG will transfer all information, data, and assets related exclusively to Vyleesi, including, but not limited to, existing inventory. AMAG will provide certain transitional services to Palatin for a period of time to ensure continued patient access to Vyleesi and regulatory compliance during the transition back to Palatin. Palatin will reimburse AMAG for the agreed upon costs of the transition services.

Palatin is exploring its options pertaining to enhancing the commercialization of Vyleesi, including but not limited to, discussions with potential collaboration partners that currently market female healthcare products. Palatin continues collaboration discussions for territories outside the currently licensed territories of China and Korea and anticipates executing multiple agreements through calendar year 2021.

In the interim, the Company's strategy implements an informed and highly targeted approach to marketing, focusing on telemedicine, social media, and digital advertising. The Company is committed to working with payers and healthcare professionals to ensure women with HSDD have continued and affordable access to Vyleesi. Vyleesi remains commercially available through specialty pharmacies Avella and BioPlus. Patients also have the ability to connect with a healthcare provider through telemedicine. Patients and healthcare providers can learn more about HSDD and Vyleesi at www.vyleesi.com.

-More-

Vyleesi is the first FDA-approved product for the as-needed treatment for premenopausal women who experience distress or interpersonal difficulty due to low sexual desire. This treatment is available as a subcutaneous self-injection in a prefilled disposable autoinjector pen for use in anticipation of a sexual encounter.

Anti-Inflammatory / Autoimmune Programs

Enrollment in a Phase 2 clinical study with PL9643 was completed in August 2020. Data readout is targeted for the fourth calendar quarter of 2020. If results from the Phase 2 study support advancing to Phase 3, the Company will initiate a Phase 3 efficacy study as early as mid-calendar year 2021.

A Phase 2 proof-of-concept clinical study with an oral formulation of PL8177 in ulcerative colitis patients is targeted to start in the first half of calendar year 2021, with data readout potentially in the first half of calendar year 2022.

The Company continues its assessment and development work related to the treatment of patients with diabetic retinopathy, with an IND targeted for mid-calendar year 2021.

The Company currently anticipates filing an IND and commencing clinical trials with PL8177 for non-infectious uveitis, for which FDA granted orphan drug designation, in the second half of calendar year 2021.

Palatin is advancing its COVID-19 development plan and is conducting all the required activities needed to file an IND and begin clinical studies with PL8177 in COVID-19 patients. These activities will be completed in the fourth calendar quarter of 2020, allowing the Company to potentially file an IND with the FDA and initiate a clinical study of PL8177 for the treatment of COVID-19 patients early in the first calendar quarter of 2021.

The landscape for treating and conducting clinical studies in COVID-19 patients is rapidly evolving. This impacts the design, risk, and ability to conduct clinical studies in COVID-19 patients. Considering the risk and uncertainty of conducting COVID-19 clinical studies, the start of a PL8177 clinical study is subject to receiving external funding and operational support. The Company is in the process of applying to government programs that provide such support.

Natriuretic Peptide Receptor (NPR) System Program

PL3994, an NPR-A agonist, will be evaluated in a Phase 2A clinical study in heart failure patients with preserved ejection fraction. The proposed study is a collaboration with two major academic medical centers and is supported by an American Heart Association grant. The study is now anticipated to start patient enrollment in the fourth calendar quarter of 2020

Genetic Obesity Program

Palatin's melanocortin receptor 4 (MC4r) peptide PL8905 and orally active small molecule PL9610 are currently under investigation for the treatment of rare genetic metabolic and obesity disorders. These programs are under internal evaluation for orphan designations, potential development, and licensing.

Fourth Quarter and Fiscal Year 2020 Financial Results

Revenue

Palatin recognized no revenues for the quarter ended June 30, 2020 and $117,989 in license and contract revenue for the year ended June 30, 2020 related to our license agreement with AMAG.

For the quarter and year ended June 30, 2019, Palatin recognized $60.3 million in license and contract revenue related to our license agreement with AMAG.

Operating Expenses

Total operating expenses for the quarter ended June 30, 2020 were $7.4 million compared to $8.1 million for the comparable quarter of 2019. The decrease in operating expenses was due to the overall reduction in research and development expenses and a decrease in general and administrative expenses.

For the year ended June 30, 2020, Palatin incurred $23.7 million of operating expenses, compared to $24.6 million for the year ended June 30, 2019. The decrease in operating expenses was due to the overall reduction in research and development expenses offset by an increase in general and administrative expenses.

Other Income/Expense, net

Total other income, net, for the quarter and year ended June 30, 2020 was $90,667 and $1.2 million, respectively.

Total other income, net, for the quarter and year ended June 30, 2019 was $38,476 and $28,707, respectively.

The difference is related primarily to the increase in investment income and secondarily to the decrease in interest expense related to venture debt.

Cash Position

Palatin's cash and cash equivalents were $82.9 million with no accounts receivable as of June 30, 2020, compared to cash and cash equivalents of $43.5 with accounts receivable of $60.3 million at June 30, 2019.

Management believes that its existing capital resources will be sufficient to fund the Company's planned operations through at least September 30, 2021.

Conference Call / Webcast

Palatin will host a conference call and audio webcast on September 28, 2020 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 1-800-353-6461 (US/Canada) or 1-334-323-0501 (international), conference ID 6978729. 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 audio 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 6978729. The webcast and telephone replay will be available through October 5, 2020.

-More-

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, Palatin's ongoing relationship with AMAG, market potential for product candidates, and potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, 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 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, transfer of marketing and sale of Vyleesi in North America to another pharmaceutical company, sales of Vyleesi in the United States and elsewhere in the world, results of clinical trials, regulatory actions by the FDA and other regulatory 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.

Investor Inquiries:
Stephen T. Wills, CPA, MST
CFO/COO (609) 495-2200
Info@Palatin.com

Media Inquiries:
Paul Arndt, MBA, LifeSci Advisors
Managing Director (646) 597-6992
Paul@LifeSciAdvisors.com

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(Financial Statement Data Follows)

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

	Three Months Ended June 30,		Year Ended June 30,	
	2020	2019	2020	2019
REVENUES				
License and contract	$ -	$ 60,265,971	$ 117,989	$ 60,300,476
OPERATING EXPENSES				
Research and development	3,933,034	4,328,766	13,959,397	14,857,095
General and administrative	3,456,805	3,751,118	9,765,372	9,699,061
Total operating expenses	7,389,839	8,079,884	23,724,769	24,556,156
(Loss) income from operations	(7,389,839)	52,186,087	(23,606,780)	35,744,320
OTHER INCOME (EXPENSE)				
Investment income	98,977	85,056	1,200,898	446,268
Interest expense	(8,310)	(46,580)	(20,141)	(417,561)
Total other income (expense), net	90,667	38,476	1,180,757	28,707
(Loss) income before income taxes	(7,299,172)	52,224,563	(22,426,023)	35,773,027
Income tax expense	-	-	-	-
NET (LOSS) INCOME	$ (7,299,172)	$ 52,224,563	$ (22,426,023)	$ 35,773,027
Basic net (loss) income per common share	$ (0.03)	$ 0.25	$ (0.10)	$ 0.17
Diluted net (loss) income per common share	$ (0.03)	$ 0.23	$ (0.10)	$ 0.16
Weighted average number of common shares outstanding used in computing basic net (loss) income per common share	235,394,831	212,253,194	234,684,776	207,670,607
Weighted average number of common shares outstanding used in computing diluted net (loss) income per common share	235,394,831	228,526,106	234,684,776	217,133,374

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(Financial Statement Data Follows)

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

	June 30, 2020	June 30, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,852,270	$ 43,510,422
Accounts receivable	-	60,265,970
Prepaid expenses and other current assets	738,216	637,289
Total current assets	83,590,486	104,413,681
Property and equipment, net	140,216	141,539
Right-of-use assets *	1,266,132	-
Other assets	56,916	179,916
Total assets	$ 85,053,750	$ 104,735,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 715,672	$ 504,787
Accrued expenses	2,899,097	2,848,692
Notes payable, net of discount	-	332,896
Short-term operating lease liabilities *	312,784	-
Other current liabilities	-	499,517
Total current liabilities	3,927,553	4,185,892
Long-term operating lease liabilities *	953,348	-
Total liabilities	4,880,901	4,185,892
Stockholders' equity:		
Preferred stock of $0.01 par value – authorized 10,000,000 shares; shares issued and outstanding designated as follows:		
Series A Convertible: authorized 264,000 shares: issued and outstanding 4,030 shares as of June 30, 2020 and June 30, 2019	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 229,258,400 shares as of June 30, 2020 and 226,815,363 shares as of June 30, 2019	2,292,584	2,268,154
Additional paid-in capital	396,079,127	394,053,929
Accumulated deficit	(318,198,902)	(295,772,879)
Total stockholders' equity	80,172,849	100,549,244
Total liabilities and stockholders' equity	$ 85,053,750	$ 104,735,136

* In the first quarter of fiscal 2020, the Company adopted Accounting Standards Update No. 2016-02, *Leases*. Under the new standard, lessees are required to recognize right-of-use assets and lease liabilities on the balance sheet for all leases. The Company adopted this standard using a modified retrospective transition method and elected the option to not restate comparative periods.