SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 8-K

Date Filed: 2020-11-17

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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): **November 17, 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 November 17, 2020, we issued a press release including results for our first quarter ended September 30, 2020 and announcing a teleconference and webcast to be held November 17, 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 November 17, 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: November 17, 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 November 17, 2020

Palatin Technologies, Inc. Reports First Quarter

Fiscal Year 2021 Results and Provides Business Update

- *Regained North American Rights to Vyleesi® for HSDD with Palatin Receiving $12 Million from AMAG Plus $4.3 Million Due March 31, 2021*
- *Phase 2 Clinical Results of PL9643 for the Treatment of Dry Eye Disease on Track for December 2020*
  - *$86.6 Million in Cash and Cash Equivalents as of September 30, 2020*
  - *Conference Call Today at 11:00 AM ET*

CRANBURY, NJ – November 17, 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 results for its first quarter ended September 30, 2020.

First Quarter Ended September 30, 2020 Financial Highlights

- Net loss for the quarter was $(3.9) million, or $(0.02) per share, compared to a net loss of $(4.5) million, or $(0.02) per share for the comparable quarter of 2019;
- Vyleesi® gross sales for the period July 25 to September 30 amounted to $809,100. Recognized $(288,560) in Vyleesi product revenue, net of allowances and accruals;
- Recognized no contract and license revenue for the quarter, compared to $97,379 for the comparable quarter of 2019;
- Total operating expenses for the quarter were $3.7 million, including a $1.6 million gain on the license termination agreement, compared to $5.0 million for the comparable quarter of 2019;
- As of September 30, 2020, the Company had $86.6 million in cash and cash equivalents and $5.0 million in accounts receivable, compared to $82.9 million in cash and cash equivalents and no accounts receivable as of June 30, 2020, with no outstanding debt.

Business Highlights and Updates

- In July 2020, regained exclusive North American rights to market Vyleesi® (bremelanotide injection), 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;
- Vyleesi commercial activities: solidified the distribution network and procedures, improved contact with prescribers and healthcare providers through virtual meetings, increased insurance reimbursement coverage, and initiated a highly-selective digital marketing and telemedicine campaign to rebuild awareness and demand among pre-menopausal women with initial geo-targeting to top prescriber and digital locations;
- Completed enrollment of a Phase 2 clinical study with PL9643 for the treatment of dry eye disease (DED). Data readout expected December 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.

“We have made significant progress and improvement on Vyleesi commercial activities, specifically around insurance reimbursement and expanded coverage. This put us in the proper position as we initiated a targeted marketing digital campaign to raise condition and treatment awareness with premenopausal women,” stated Carl Spana, Ph.D., President and CEO of Palatin.

"Despite the challenges posed by the ongoing viral pandemic, we are on track for data readout next month on our PL9643 Phase 2 clinical study in subjects with dry eye disease. Most people living with dry eye disease suffer from episodic flare-ups. These flares can be caused by a multitude of triggers and frequently are not sufficiently addressed by current therapies.”

Programs Overview

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

In July 2020, Palatin announced the mutual termination of its License Agreement with AMAG Pharmaceutical, Inc, for Vyleesi. Under 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 transferred information, data, and assets related exclusively to Vyleesi, including existing inventory. AMAG is providing certain transitional services to Palatin for a period to ensure continued patient access to Vyleesi and regulatory compliance during the transition back to Palatin. Palatin is reimbursing AMAG for the agreed upon costs of the transition services.

Palatin is exploring its options to enhance the commercialization of Vyleesi, including 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.

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 can connect with a healthcare provider through telemedicine. Patients and healthcare providers can learn more about HSDD and Vyleesi at www.vyleesi.com.

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 for the treatment of dry eye disease was completed in August 2020. Data readout is targeted for December 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 investigational new drug (IND) filing 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 the 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 as a treatment 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. Patient enrollment in the study has commenced and the first patient was dosed in November 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.

Conference Call / Webcast

Palatin will host a conference call and audio webcast on November 17, 2020 at 11:00 a.m. Eastern Time to discuss the quarter ended September 30, 2020 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 3383273. 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 3383273. The webcast and telephone replay will be available through November 24, 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 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, Palatin's ability to establish and maintain the capability for manufacturing, marketing and distribution of Vyleesi, 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.

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(Financial Statement Data Follows)

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

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

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

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