

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 8-K

Date Filed: 2021-02-17

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): **February 17, 2021**

Palatin Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-15543
(Commission
File Number)

95-4078884
(IRS employer
identification number)

4B Cedar Brook Drive, Cranbury, NJ
(Address of principal executive offices)

08512
(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
Common Stock, par value \$.01 per share

Trading Symbol
PTN

Name of Each Exchange
on Which Registered
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 February 17, 2021, we issued a press release including results for our second quarter ended December 31, 2020 and announcing a teleconference and webcast to be held February 17, 2021 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 17, 2021

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 17, 2021

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 17, 2021

Palatin Technologies, Inc. Reports Second Quarter

Fiscal Year 2021 Financial Results and Recent Business Highlights

- *Positive Results from Phase 2 Clinical Study of PL9643 in Patients with Dry Eye Disease*
- *Continue to Rebuild Commercial Infrastructure and Brand Awareness for Vyleesi®*
- *Approximately \$72.2 Million in Cash and Cash Equivalents at*

December 31, 2020

- *Teleconference and Webcast to be held on February 17, 2021 at 11:00 AM ET*

CRANBURY, NJ – February 17, 2021 – 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 second quarter ended December 31, 2020.

Second Quarter Ended December 31, 2020 Financial Highlights

- Net loss for the quarter was \$(10.0) million, or \$(0.04) per share, compared to a net loss of \$(5.2) million, or \$(0.02) per share for the comparable quarter of 2019;
 - The increase in net loss was primarily attributable to commercial expenses related to Vyleesi and to PL9643's Phase 2 study for the treatment of dry eye disease.
- As of December 31, 2020, the Company had \$72.2 million in cash and cash equivalents and \$4.7 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

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

- Vyleesi gross sales for the quarter ended December 31, 2020 amounted to \$943,950. Vyleesi product revenue was \$(163,971), net of allowances and accruals. Vyleesi gross sales for the period July 25 to September 30 amounted to \$809,100. Vyleesi product revenue was \$(288,560), net of allowances and accruals;
- Restructured the distribution network and procedures improving the patient experience; expanded 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 a geo-targeting approach.

● **Anti-Inflammatory / Autoimmune Programs**

- Announced positive results in its Phase 2 study of PL9643 for the treatment of dry eye disease (DED);
 - Announced statistically significant improvements in multiple signs and symptoms in the moderate to severe patient population after 2 weeks of dosing and at the 12-week visit.
 - There were no safety signals identified and PL9643 had excellent ocular tolerability.
 - Statistical significance for the primary endpoints was not reached in the overall enrolled population that included mild, moderate, and severe patients, as measured at the 12-week primary evaluation visit.
 - A Phase 2/3 Clinical trial with PL9643 for the treatment of DED is currently planned for mid-calendar year 2021;
 - Filed an international patent application under the Patent Cooperation Treaty (PCT) directed to the composition of PL9643 and a related family of melanocortin agonist peptides; and
 - A Phase 2 proof-of-concept clinical study with an oral formulation of PL8177 in ulcerative colitis patients is targeted to start mid-calendar year 2021, with data readout potentially in mid-calendar year 2022.
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"Working through the melanocortin system, PL9643 is a novel approach to treating dry eye disease. The emerging profile of PL9643, with its rapid therapeutic onset and excellent tolerability profile, is a potentially distinct advance in dry eye therapy," stated Carl Spana, Ph.D., President and CEO of Palatin. " The positive PL9643 Phase 2 study results identify the most appropriate patient population, endpoints, and timepoints for the next study, which is a Phase 2/3 study targeted for mid-calendar year 2021, with data readout in the first half of calendar year 2022. Regarding Vyleesi, our measured plan and investment is showing positive trends and returns with a significant rise in payer reimbursement and double-digit increases to month over month prescription numbers continuing through January 2021."

Conference Call / Webcast

Palatin will host a conference call and audio webcast on February 17, 2021 at 11:00 a.m. Eastern Time to discuss the quarter ended December 31, 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 1-866-248-8441 (US/Canada) or 1-856-344-9206 (international), conference ID 2203098. 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 2203098. The webcast and telephone replay will be available through February 24, 2021.

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 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 market potential of Palatin's products, clinical trial results, potential actions by regulatory agencies including the FDA, regulatory plans, development programs, proposed indications for product candidates, Palatin's ability to manufacture and market Vyleesi, 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, 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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Palatin Technologies® and Vyleesi® are registered trademarks of Palatin Technologies, Inc.

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(Financial Statement Data Follows)

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

	<u>Three Months Ended December 31,</u>		<u>Six Months Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
REVENUES				
Product revenue, net	\$ (163,971)	\$ -	\$ (452,531)	\$ -
License and contract	-	20,610	-	117,989
	<u>(163,971)</u>	<u>20,610</u>	<u>(452,531)</u>	<u>117,989</u>
OPERATING EXPENSES				
Cost of products sold	29,400	-	54,600	-
Research and development	4,011,418	3,257,624	6,935,269	6,385,113
Selling, general and administrative	5,044,913	2,404,093	7,376,519	4,236,535
Gain on license termination agreement	-	-	(1,623,795)	-
Total operating expenses	<u>9,085,731</u>	<u>5,661,717</u>	<u>12,742,593</u>	<u>10,621,648</u>
Loss from operations	<u>(9,249,702)</u>	<u>(5,641,107)</u>	<u>(13,195,124)</u>	<u>(10,503,659)</u>
OTHER (EXPENSE) INCOME				
Investment income	4,800	399,982	16,935	770,636
Foreign currency loss	(745,002)	-	(745,002)	-
Interest expense	(1,871)	(2,502)	(9,360)	(11,553)
Total other (expense) income, net	<u>(742,073)</u>	<u>397,480</u>	<u>(737,427)</u>	<u>759,083</u>
NET LOSS	<u>\$ (9,991,775)</u>	<u>\$ (5,243,627)</u>	<u>\$ (13,932,551)</u>	<u>\$ (9,744,576)</u>
Basic and diluted net loss per common share				
	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.06)</u>	<u>\$ (0.04)</u>
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share				
	<u>236,405,065</u>	<u>234,923,592</u>	<u>236,375,463</u>	<u>234,018,417</u>

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

	<u>December 31,</u> <u>2020</u>	<u>June 30, 2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 72,156,110	\$ 82,852,270
Accounts receivable	4,746,623	-
Inventories	6,031,088	-
Prepaid expenses and other current assets	2,556,911	738,216
Total current assets	85,490,732	83,590,486
Property and equipment, net	116,362	140,216
Right-of-use assets	1,113,685	1,266,132
Other assets	56,916	56,916
Total assets	\$ 86,777,695	\$ 85,053,750
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,174,493	\$ 715,672
Accrued expenses	4,799,561	2,899,097
Short-term operating lease liabilities	265,339	312,784
Other current liabilities	1,010,250	-
Total current liabilities	7,249,643	3,927,553
Long-term operating lease liabilities	855,626	953,348
Other long-term liabilities	10,837,300	-
Total liabilities	18,942,569	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 December 31, 2020 and June 30, 2020	40	40
Common stock of \$0.01 par value – authorized 300,000,000 shares: issued and outstanding 230,034,307 shares as of December 31, 2020 and 229,258,400 shares as of June 30, 2020	2,300,343	2,292,584
Additional paid-in capital	397,666,196	396,079,127
Accumulated deficit	(332,131,453)	(318,198,902)
Total stockholders' equity	67,835,126	80,172,849
Total liabilities and stockholders' equity	\$ 86,777,695	\$ 85,053,750