

PALATIN TECHNOLOGIES INC
Form 10-Q
November 12, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015

or

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-15543

PALATIN TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

95-4078884
(I.R.S. Employer Identification
No.)

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

08512
(Zip Code)

(609) 495-2200

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

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to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 10, 2015, 68,030,008 shares of the registrant's common stock, par value \$0.01 per share, were outstanding.

PALATIN TECHNOLOGIES, INC.
Table of Contents

	Page
PART I – FINANCIAL INFORMATION	
Item 1. Financial Statements (Unaudited)	
Consolidated Balance Sheets as of September 30, 2015 and June 30, 2015	3
Consolidated Statements of Operations for the Three Months Ended September 30, 2015 and 2014	4
Consolidated Statements of Cash Flows for the Three Months Ended September 30, 2015 and 2014	5
Notes to Consolidated Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures About Market Risk	16
Item 4. Controls and Procedures	16
PART II – OTHER INFORMATION	
Item 1. Legal Proceedings	17
Item 1A. Risk Factors	17
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	35
Item 3. Defaults Upon Senior Securities	35
Item 4. Mine Safety Disclosures	35
Item 5. Other Information	35
Item 6. Exhibits	36
Signatures	37

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this quarterly report on Form 10-Q, as well as oral statements that may be made by us or by our officers, directors, or employees acting on our behalf, that are not historical facts constitute “forward-looking statements”, which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). The forward-looking statements in this quarterly report on Form 10-Q do not constitute guarantees of future performance. Investors are cautioned that statements that are not strictly historical statements contained in this quarterly report on Form 10-Q, including, without limitation, the following are forward looking statements:

- estimates of our expenses, future revenue, capital requirements;
- our ability to obtain additional financing on terms acceptable to us, or at all;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals;
- our expectations regarding the results and the timing of results in our Phase 3 clinical trials of bremelanotide for female sexual dysfunction, or FSD;
- our expectation regarding the timing of our regulatory submissions for approval of bremelanotide for FSD in the United States and Europe;
- the potential for commercialization of bremelanotide for FSD and other product candidates, if approved, by us;
- our expectations regarding the potential market size and market acceptance for bremelanotide for FSD and our other product candidates, if approved for commercial use;
- our ability to compete with other products and technologies similar to our product candidates;
- the ability of our third-party collaborators to timely carry out their duties under their agreements with us;
- the ability of our contract manufacturers to perform their manufacturing activities for us in compliance with applicable regulations;
- our ability to recognize the potential value of our licensing arrangements with third parties;
- the potential to achieve revenues from the sale of our product candidates;
- our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers;
- our ability to maintain product liability insurance at a reasonable cost or in sufficient amounts, if at all;
- the retention of key management, employees and third-party contractors;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our compliance with federal and state laws and regulations;
- the timing and costs associated with obtaining regulatory approval for our product candidates;
- the impact of fluctuations in foreign exchange rates;
- the impact of legislative or regulatory healthcare reforms in the United States;
- our ability to adapt to changes in global economic conditions; and
- our ability to remain listed on the NYSE MKT.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. Our future operating results are subject to risks and uncertainties and are dependent upon many factors, including, without limitation, the risks identified in this report, in our annual report on Form 10-K for the year ended June 30, 2015, and in our other Securities and Exchange Commission (SEC) filings.

We expect to incur losses in the future as a result of spending on our planned development programs and results may fluctuate significantly from quarter to quarter.

PART I - FINANCIAL INFORMATION