PALATIN TECHNOLOGIES INC
Form 10-Q
November 14, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

or

o 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	95-4078884
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4B Cedar Brook Drive Cranbury, New Jersey	08512
(Address of principal executive offices)	(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 þ 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 to submit and post such files). Yes þ 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 ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company þ

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

As of November 13, 2014, 39,490,161 shares of the registrant's common stock, par value $.01 per share, were outstanding.

PALATIN TECHNOLOGIES, INC.
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2014	June 30, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$17,787,720	$12,184,605
Prepaid expenses and other current assets	473,643	156,393
Total current assets	18,261,363	12,340,998
Property and equipment, net	133,155	160,748
Other assets	57,088	57,308
Total assets	$18,451,606	$12,559,054
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$561,361	$261,280
Accrued expenses	2,160,407	1,508,958
Deferred revenue	4,932,315	1,000,000
Total current liabilities	7,654,083	2,770,238
Total liabilities	7,654,083	2,770,238
Stockholders' equity:		
Preferred stock of $0.01 par value – authorized 10,000,000 shares;		
Series A Convertible; issued and outstanding 4,697 shares as of September 30, 2014 and June 30, 2014, respectively	47	47
Common stock of $0.01 par value – authorized 300,000,000 shares;		
issued and outstanding 39,490,161 shares as of September 30, 2014 and 39,416,595 as of June 30, 2014, respectively	394,901	394,166
Additional paid-in capital	283,641,654	283,428,356
Accumulated deficit	(273,239,079)	(274,033,753)
Total stockholders' equity	10,797,523	9,788,816
Total liabilities and stockholders' equity	$18,451,606	$12,559,054

The accompanying notes are an integral part of these consolidated financial statements.

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

	Three Months Ended September 30,	
	2014	2013
REVENUES:		
License revenue	$4,932,315	$-
OPERATING EXPENSES:		
Research and development	2,923,966	3,449,140
General and administrative	1,114,461	1,043,510
Total operating expenses	4,038,427	4,492,650
Income (loss) from operations	893,888	(4,492,650)
OTHER INCOME (EXPENSE):		
Investment income	3,799	5,319
Interest expense	(1,730)	(1,851)
Foreign exchange transaction loss	(101,283)	-
Total other (expense) income, net	(99,214)	3,468
NET INCOME (LOSS)	$794,674	$(4,489,182)
Basic net income (loss) per common share	$0.01	$(0.04)
Diluted net income (loss) per common share	$0.01	$(0.04)
Weighted average number of common shares outstanding used in computing basic net income (loss) per common share	106,953,898	106,609,720
Weighted average number of common shares outstanding used in computing diluted net income (loss) per common share	107,946,021	106,609,720

The accompanying notes are an integral part of these consolidated financial statements.

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

	Three Months Ended September 30,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$794,674	$(4,489,182)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	27,593	27,242
Accrued interest and amortization on premium/discount	-	(272)
Stock-based compensation	252,471	203,636
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(9,285)	80,770
Accounts payable	300,081	652,172
Accrued expenses	427,334	480,390
Deferred revenue	3,932,315	1,000,000
Net cash provided by (used in) operating activities	5,725,183	(2,045,244)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturity of investments	-	1,500,000
Purchases of property and equipment	-	(6,239)
Net cash provided by investing activities	-	1,493,761
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on capital lease obligations	-	(5,841)
Payment of withholding taxes related to restricted stock units	(122,068)	(25,215)
Net cash used in financing activities	(122,068)	(31,056)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,603,115	(582,539)
CASH AND CASH EQUIVALENTS, beginning of period	12,184,605	19,167,632
CASH AND CASH EQUIVALENTS, end of period	$17,787,720	$18,585,093
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$1,730	$1,851

The accompanying notes are an integral part of these consolidated financial statements.

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

(1) ORGANIZATION:

Nature of Business – Palatin Technologies, Inc. (Palatin or the Company) is a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Palatin's programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. The melanocortin system is involved in a large and diverse number of physiologic functions, and therapeutic agents modulating this system may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, cachexia (wasting syndrome) and inflammation-related diseases. The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of acute asthma, heart failure, hypertension and other cardiovascular diseases.

The Company's primary product in development is bremelanotide for the treatment of female sexual dysfunction (FSD). The Company also has drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases. The Company has a license, co-development and commercialization agreement with Gedeon Richter Plc. (Gedeon Richter) to commercialize bremelanotide for FSD in Europe and selected countries, and an exclusive global research collaboration and license agreement with AstraZeneca AB (AstraZeneca) to commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome.

Key elements of the Company's business strategy include using its technology and expertise to develop and commercialize innovative therapeutic products; entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that the Company is developing; and partially funding its product candidate development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties.

Business Risk and Liquidity – The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company has an accumulated deficit as of September 30, 2014 of $273.2 million and despite reporting net income the three months ended September 30, 2014 of $0.8 million, the Company anticipates incurring additional losses in the future as a result of spending on its development programs. To achieve profitability, if ever, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct successful preclinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and there can be no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

As of September 30, 2014, the Company's cash and cash equivalents were $17.8 million. The Company intends to utilize existing capital resources for general corporate purposes and working capital, including advancing the Phase 3 clinical trial program with bremelanotide for FSD and preclinical and clinical development of our other product candidates and programs, including PL-3994 and melanocortin receptor-1 and melanocortin receptor-4 programs. Management believes that the Phase 3 clinical trial program with bremelanotide, including regulatory filings for product approval, will cost at least $80.0 million. The Company is preparing to initiate patient enrollment in

the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless the Company has adequate funds, or commitments for adequate funds, to complete the Phase 3 clinical trials. The Company intends to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide, in addition to the Company's agreement with Gedeon Richter, public or private equity or debt financings, or other sources.

Management believes that the Company's existing capital resources will be adequate to fund its planned operations through the quarter ending December 31, 2015, not including initiation of its pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials.

Concentrations – Concentrations in the Company's assets and operations subject it to certain related risks. Financial instruments that subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents. The Company's cash and cash equivalents are primarily invested in one money market fund sponsored by a large financial institution. For the three months ended September 30, 2014, 100% of revenues were from Gedeon Richter. For the three months ended September 30, 2013, the Company had no revenues.

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

(2) BASIS OF PRESENTATION:

The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnote disclosures required to be presented for complete financial statements. In the opinion of management, these consolidated financial statements contain all adjustments (consisting of normal recurring adjustments) considered necessary for fair presentation. The results of operations for the three months ended September 30, 2014 may not necessarily be indicative of the results of operations expected for the full year, except that the Company expects to incur a significant loss for the fiscal year ending June 30, 2015.

The accompanying consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended June 30, 2014, filed with the Securities and Exchange Commission (SEC), which includes consolidated financial statements as of June 30, 2014 and 2013 and for each of the fiscal years in the three-year period ended June 30, 2014.

(3) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Principles of Consolidation – The consolidated financial statements include the accounts of Palatin and its wholly-owned inactive subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates – The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents – Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a purchased maturity of less than three months. Cash equivalents consist of $15,103,388 and $9,495,656 in a money market fund at September 30, 2014 and June 30, 2014, respectively.

Fair Value of Financial Instruments – The Company's financial instruments consist primarily of cash equivalents and accounts payable. Management believes that the carrying value of these assets and liabilities are representative of their respective fair values based on quoted market prices for investments and the short-term nature of the other instruments.

Property and Equipment – Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements and includes assets acquired under capital leases. Property and equipment are recorded at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets, generally five years for laboratory and computer equipment, seven years for office furniture and equipment and the lesser of the term of the lease or the useful life for leasehold improvements. Amortization of assets acquired under capital leases is included in depreciation expense. Maintenance and repairs are expensed as incurred while expenditures that extend the useful life of an asset are capitalized.

Impairment of Long-Lived Assets – The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine recoverability of a long-lived asset, management evaluates whether the estimated future undiscounted net cash flows from the asset are less than its carrying amount. If impairment is indicated, the long-lived asset would be written down to fair value. Fair value is determined by an evaluation of available price information at which assets could be bought or sold, including quoted market prices if available, or the present value of the estimated future cash flows based on reasonable and supportable assumptions.

Deferred Rent – The Company's operating leases provide for rent increases over the terms of the leases. Deferred rent consists of the difference between periodic rent payments and the amount recognized as rent expense on a straight-line basis, as well as tenant allowances for leasehold improvements. Rent expenses are being recognized ratably over the terms of the leases.

Revenue Recognition – Under our license, co-development and commercialization agreement with Gedeon Richter (note 6), we may be entitled to receive consideration in the form of license fees, regulatory milestone payments, sales milestone payments, and royalties.

Revenue resulting from license fees is recognized upon delivery of the license for the portion of the license fee payment that is non-contingent and non-refundable, if the license has standalone value. Revenue resulting from the achievement of development milestones are recorded in accordance with the accounting guidance for the milestone method of revenue recognition. Revenue resulting from the achievement of sales milestone events is recognized when the milestone is achieved. Revenue from royalties is recorded when earned.

PALATIN TECHNOLOGIES, INC.
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Notes to Consolidated Financial Statements
(unaudited)

Research and Development Costs – The costs of research and development activities are charged to expense as incurred, including the cost of equipment for which there is no alternative future use.

Accrued Expenses – Third parties perform a significant portion of our development activities. We review the activities performed under significant contracts each quarter and accrue expenses and the amount of any reimbursement to be received from our collaborators based upon the estimated amount of work completed. Estimating the value or stage of completion of certain services requires judgment based on available information.

Stock-Based Compensation – The Company charges to expense the fair value of stock options and other equity awards granted. The Company determines the value of stock options utilizing the Black-Scholes option pricing model. Compensation costs for share-based awards with pro rata vesting are allocated to periods on a straight-line basis.

Income Taxes – The Company and its subsidiary file consolidated federal and separate-company state income tax returns. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences or operating loss and tax credit carryforwards are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The Company has recorded a valuation allowance against its deferred tax assets based on the history of losses incurred.

Net Income (Loss) per Common Share – Basic and diluted earnings per common share (EPS) are calculated in accordance with the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 260, “Earnings per Share,” which includes guidance pertaining to the warrants, issued in connection with the July 3, 2012 private placement offering, that are exercisable for nominal consideration and, therefore, are to be considered in the computation of basic and diluted net loss per common share. The Series A 2012 warrants to purchase up to 31,988,151 shares of common stock were exercisable starting at July 3, 2012 and, therefore, are included in the weighted average number of common shares outstanding used in computing basic and diluted net income (loss) per common share starting on July 3, 2012.

The Series B 2012 warrants to purchase up to 35,488,380 shares of common stock were considered contingently issuable shares and were not included in computing basic net loss per common share until the Company received stockholder approval for the increase in authorized underlying common stock on September 27, 2012. For diluted EPS, contingently issuable shares are to be included in the calculation as of the beginning of the period in which the conditions were satisfied, unless the effect would be anti-dilutive. The Series B 2012 warrants have been excluded from the calculation of diluted net loss per common share during the period from July 3, 2012 until September 27, 2012 as the impact would be anti-dilutive.

The following table is a reconciliation of net income (loss) and the shares used in calculating basic and diluted net income (loss) per common share for the three months ended September 30, 2014 and 2013:

	Three Months Ended September 30,	
	2014	2013
Numerator:		
Net income (loss)	$794,674	$(4,489,182)
Denominator:		
Weighted average common shares outstanding - Basic	106,953,898	$106,609,720
Effect of dilutive shares:		
Common stock equivalents arising from stock options and warrants	799,139	-
Restricted stock units	192,984	-
Weighted average common shares outstanding - Diluted	107,946,021	106,609,720
Net income (loss) per common share:		
Basic	$0.01	$(0.04)
Diluted	$0.01	$(0.04)

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(unaudited)

As of September 30, 2014 and 2013, common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding options and warrants (excluding the warrants issued in connection with the July 3, 2012 private placement offering), and the vesting of restricted stock units amounted to an aggregate of 28,903,674 and 28,677,356 shares, respectively, and are excluded in the weighted average number of common shares outstanding used in computing basic net income (loss) per common share. For the three months ended September 30, 2014, an additional 992,123 of common shares have been included in the computation of diluted EPS. However, for the three months ended September 30, 2013, no additional common shares were added in the computation of diluted EPS because to do so would have been anti-dilutive for this period.

(4) NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS:

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements-Going Concern: Disclosures of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” The amendments in this update provide guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The new standard is effective for the Company for its fiscal year ending June 30, 2017. The Company is evaluating the effect of the standard, if any, on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers,” which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on July 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet determined the effect of the standard on its ongoing financial reporting.

(5) AGREEMENT WITH ASTRAZENECA:

In January 2007, the Company entered into an exclusive global research collaboration and license agreement with AstraZeneca to discover, develop and commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome. In June 2008, the license agreement was amended to include additional compounds and associated intellectual property developed by the Company. In December 2008, the license agreement was further amended to include additional compounds and associated intellectual property developed by the Company and extended the research collaboration for an additional year through January 2010. In September 2009, the license agreement was further amended to modify royalty rates and milestone payments. The collaboration is based on the Company’s melanocortin receptor obesity program and includes access to compound libraries, core technologies and expertise in melanocortin receptor drug discovery and development. As part of the September 2009 amendment to the research collaboration and license agreement, the Company agreed to conduct additional studies on the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters.

In December 2009 and 2008, the Company also entered into clinical trial sponsored research agreements with AstraZeneca, under which the Company agreed to conduct studies of the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters. Under the terms of these clinical trial agreements, AstraZeneca paid $5,000,000 as of March 31, 2009 upon achieving certain objectives and paid all costs associated with these studies.

The Company received an up-front payment of $10,000,000 from AstraZeneca on execution of the research collaboration and license agreement. Under the September 2009 amendment the Company was paid an additional $5,000,000 in consideration of reduction of future milestones and royalties and providing specific materials to AstraZeneca. The Company is now eligible for milestone payments totaling up to $145,250,000, with up to $85,250,000 contingent on development and regulatory milestones and the balance contingent on achievement of sales targets. In addition, the Company is eligible to receive mid to high single digit royalties on sales of any approved products. AstraZeneca assumed responsibility for product commercialization, product discovery and development costs, with both companies contributing scientific expertise in the research collaboration. The Company provided research services to AstraZeneca through January 2010, the expiration of the research collaboration portion of the research collaboration and license agreement, at a contractual rate per full-time-equivalent employee.

AstraZeneca is evaluating its program and next steps. No assurance can be given that AstraZeneca will continue to develop compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome, or that AstraZeneca will be successful in developing any such compound.

PALATIN TECHNOLOGIES, INC.
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Notes to Consolidated Financial Statements
(unaudited)

(6) AGREEMENT WITH GEDEON RICHTER:

In August 2014, the Company entered into a license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for FSD in Europe and selected countries. In August 2013, the Company received an initial payment of $1.0 million from Gedeon Richter as a non-refundable option fee on the license, co-development and commercialization agreement, and in September 2014, the Company received €6.7 ($8.8 million) on execution of the definitive agreement. Under the agreement, Gedeon Richter will pay the Company a milestone payment of €2.5 million ($3.2 million as of September 30, 2014) upon the initiation of the Company's Phase 3 clinical trial program in the United States. The Company has the potential to receive up to €80 million ($101.2 million as of September 30, 2014) in regulatory and sales related milestones, and will receive low double-digit royalties on net sales in the licensed territory. Under the agreement the Company will contribute, with Gedeon Richter, to the costs of co-development activities for obtaining regulatory approval in Europe. Gedeon Richter will exclusively market bremelanotide for FSD in the licensed territory, and will be responsible for all sales, marketing and commercial activities, including associated costs, in the licensed territory. The agreement remains in effect as long as Gedeon Richter is selling bremelanotide on which a royalty is owed. The agreement may be terminated by either party upon notice in the event of a material breach or insolvency. In the event Gedeon Richter terminates the agreement because the Company breached the agreement or is insolvent, Gedeon Richter's license becomes fully paid-up, royalty free, perpetual and irrevocable. If the Company fails to initiate its Phase 3 program on or before December 31, 2014, Gedeon Richter at its option may elect to terminate the license and receive a payment equal to one-half of the total upfront payments of €7.5 million ($9.8 million).

We view the delivery of the license for bremelanotide as a revenue generating activity that is part of our ongoing and central operations. The other elements of the agreement with Gedeon Richter are considered non-revenue activities associated with the collaborative arrangement. We believe the license has standalone value from the other elements of the collaborative arrangement because it conveys all of the rights necessary to develop and commercialize the bremelanotide compound. As of September 30, 2014, the portion of the license payment that is contingent and refundable was recorded as deferred revenue in the consolidated balance sheet. During the three months ended September 30, 2014, the portion of the license payment that is non-contingent and non-refundable was recorded as license revenue in the consolidated statements of operations. In the event that we terminate the agreement because Gedeon Richter breached the agreement or is insolvent, upon timely request all regulatory approvals for bremelanotide in the licensed territory will be transferred to us or our designee.

As a result of fluctuations in the conversion rates between the Euro and the U.S. Dollar between the transaction date and the settlement date, the Company has recorded a foreign exchange transaction loss of $101,283 for the three months ended September 30, 2014.

(7) FAIR VALUE MEASUREMENTS:

The fair value of cash equivalents are classified using a hierarchy prioritized based on inputs. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on management's own assumptions used to measure assets and liabilities at fair value. A

financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets carried at fair value:

	Carrying Value	Quoted prices in active markets (Level 1)	Other quoted/observable inputs (Level 2)	Significant unobservable inputs (Level 3)
September 30, 2014:				
Money Market Fund	$15,103,388	$15,103,388	$ -	$ -
June 30, 2014:				
Money Market Fund	$9,495,656	$9,495,656	$ -	$ -

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements
(unaudited)

(8) STOCKHOLDERS' EQUITY:

Stock Options – In June 2014, the Company granted 325,000 options to its executive officers, 143,400 options to its employees and 135,000 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $265,726, $117,247 and $97,530, respectively, over the vesting period. The Company recognized $45,219 of stock-based compensation expense related to these options during the three months ended September 30, 2014.

In June 2013, the Company granted 525,000 options to its executive officers, 394,300 options to its employees and 270,000 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $287,000, $204,000 and $148,000, respectively, over the vesting period. The Company recognized $22,471 and $66,198, respectively, of stock-based compensation expense related to these options during the three months ended September 30, 2014 and 2013.

In July 2012, the Company granted 285,000 options to its executive officers, 182,500 options to its employees and 112,500 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $182,000, $108,000 and $72,000, respectively, over the vesting period. The Company recognized $14,358 and $17,140, respectively, of stock-based compensation expense related to these options during the three months ended September 30, 2014 and 2013, respectively.

Stock options granted to the Company's executive officers and employees vest over a 48 month period, while stock options granted to its non-employee directors vest over a 12 month period.

Restricted Stock Units – In June 2014, the Company granted 325,000 restricted stock units to its executive officers, 143,400 restricted stock units to its employees and 135,000 restricted stock units to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of $331,500, $146,268 and $137,700, respectively, over the vesting period. Restricted stock units granted to the Company's executive officers, employees and non-employee directors in 2014 vest over 24 months, 48 months and 12 months, respectively. The Company recognized $115,627 of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2014.

In June 2013, the Company granted 420,000 restricted stock units to its executive officers and 115,000 restricted stock units to its employees under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of $260,000 and $71,000, respectively, over the 24 month vesting period ending June 2015. The Company recognized $18,794 and $62,194, respectively, of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2014 and 2013.

In July 2012, the Company granted 222,500 restricted stock units to its executive officers under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of $160,000 over the 24 months ending July 2014. The Company recognized $1,830 and $13,673, respectively, of stock-based compensation expense related to these restricted stock units during the three months ended September 30, 2014 and 2013, respectively.

Stock-based compensation cost for the three months ended September 30, 2014 for stock options and equity-based instruments issued other than the stock options and restricted stock units described above was $34,172, and $44,431 for the three months ended September 30, 2013.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes to the consolidated financial statements filed as part of this report and the audited consolidated financial statements and notes thereto included in our annual report on Form 10-K for the year ended June 30, 2014.

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 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 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, 2014, 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.

In this quarterly report on Form 10-Q, references to “we”, “our”, “us” or “Palatin” means Palatin Technologies, Inc. and its subsidiary.

Critical Accounting Policies and Estimates

Our significant accounting policies, which are described in the notes to our consolidated financial statements included in this report and in our annual report on Form 10-K for the year ended June 30, 2014, have not changed as of September 30, 2014. We believe that our accounting policies and estimates relating to revenue recognition, accrued expenses and stock-based compensation are the most critical.

Overview

We are a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is a combination drug-device product for the delivery of bremelanotide for the treatment of female sexual dysfunction, or FSD. In addition, we have drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

The following drug development programs are actively under development:

Bremelanotide, an on-demand subcutaneous injectable peptide melanocortin receptor agonist, for treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist (a compound which binds to a cell receptor and activates a response), is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual arousal response. Bremelanotide is scheduled to start Phase 3 clinical trials in the last quarter of calendar 2014;

Melanocortin receptor-4, or MC4r, compounds for treatment of obesity and diabetes in collaboration with AstraZeneca pursuant to our research collaboration and license agreement. Results of our studies involving MC4r peptides suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, erectile dysfunction, obesity and diabetes;

PL-3994, a peptide mimetic natriuretic peptide receptor A, or NPR-A, agonist, for treatment of cardiovascular and pulmonary indications. PL-3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone ANP. PL-3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension; and

Melanocortin receptor-1, or MC1r, agonist peptides, for treatment of inflammatory and dermatologic disease indications. Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

The following chart shows the status of our drug development programs.

We are developing subcutaneously administered bremelanotide for the treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist, is a synthetic peptide analog of the naturally occurring hormone alpha-MSH. The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual arousal response. We have completed a Phase 2B clinical trial and meetings with the FDA, and are preparing to start patient enrollment in the Phase 3 clinical trials in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete the Phase 3 clinical trials. The Phase 3 studies, which will be conducted in North America, will utilize a single-dose autoinjector intended for commercialization. It is anticipated that the Phase 3 program will take at least fifteen to eighteen months from initiation of patient dosing through database lock. Following database lock, clinical trial data will be analyzed and, assuming the data supports approval of bremelanotide for FSD, a New Drug Application (NDA) will be submitted to FDA. There can be no assurance that the Phase 3 data will support approval of bremelanotide for FSD or that the FDA will approve an NDA for bremelanotide.

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Key elements of our business strategy include:

- Using our technology and expertise to develop and commercialize products in our active drug development programs;
- Entering into strategic alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing;
- Partially funding our product development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties; and
- Completing development and seeking regulatory approval of bremelanotide for FSD and our other product candidates.

We incorporated in Delaware in 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B Cedar Brook Drive, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. We maintain an Internet site at http://www.palatin.com, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d), Section 14A and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained in it or connected to it are not incorporated into this quarterly report on Form 10-Q.

Results of Operations

Three Months Ended September 30, 2014 Compared to the Three Months Ended September 30, 2013

Revenue – For the three months ended September 30, 2014, we recognized $4.9 million in revenue pursuant to our license, co-development and commercialization agreement with Gedeon Richter. We recognized no revenue for the three months ended September 30, 2013.

In August 2014, we entered into a license, co-development and commercialization agreement with Gedeon Richter, which provided for $9.8 million in upfront payments. The non-refundable portion of the upfront payment, $4.9 million, was recorded as revenue in the three months ended September 30, 2014.

Research and Development – Research and development expenses were $2.9 million for the three months ended September 30, 2014 compared to $3.4 million for the three months ended September 30, 2013.

Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonist, obesity and other preclinical programs were $2.4 million for the three months ended September 30, 2014 compared to $2.8 million for the three months ended September 30, 2013. Spending to date has been primarily related to our bremelanotide for the treatment of FSD program. We are currently preparing for initiation of pivotal Phase 3 studies of bremelanotide. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the availability of funds to support future development activities, success of our clinical trials and preclinical and discovery programs, and our ability to progress compounds in addition to bremelanotide and PL-3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which consists mainly of compensation and related costs, were $0.5 million for the three months ended September 30, 2014 compared to $0.6 million for the three months ended September 30, 2013.

Cumulative spending from inception to March 31, 2014 is approximately $173.0 million for our bremelanotide program and approximately $120.9 million on all our other programs (which include PL-3994, other melanocortin receptor agonists, obesity, other discovery programs and terminated programs). Due to various risk factors described in our periodic filings with the SEC, including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and larger-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, net cash inflows will be generated.

General and Administrative – General and administrative expenses, which consist mainly of compensation and related costs, were $1.1 million for the three months ended September 30, 2014 compared to $1.0 million for the three September 30, 2013.

Liquidity and Capital Resources

Since inception, we have incurred net operating losses, primarily related to spending on our research and development programs. We have financed our net operating losses primarily through equity financings and amounts received under collaborative agreements.

Our product candidates are at various stages of development and will require significant further research, development and testing and some may never be successfully developed or commercialized. We may experience uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, which may include unanticipated problems and additional costs relating to:

the development and testing of products in animals and humans;
product approval or clearance;
regulatory compliance;
good manufacturing practices (GMPs);
intellectual property rights;
product introduction;
marketing, sales and competition; and
obtaining sufficient capital.

Failure to enter into collaboration agreements and obtain timely regulatory approval for our product candidates and indications would impact our ability to increase revenues and could make it more difficult to attract investment capital for funding our operations. Any of these possibilities could materially and adversely affect our operations and require us to curtail or cease certain programs.

During the three months ended September 30, 2014, cash provided by operating activities was $5.7 million, compared to cash used for operating activities of $2.0 million for the three months ended September 30, 2013. The difference for the three months ended September 30, 2014 and 2013 was primarily attributable to the upfront payment relating to the license, co-development and commercialization agreement with Gedeon Richter. Our periodic accounts payable and accrued expenses balances will continue to be highly dependent on the timing of our operating costs.

During the three months ended September 30, 2014 there were no investing activities. During the three months ended September 30, 2013, net cash provided by investing activities was $1.5 million, consisting of proceeds from the maturity of short-term investments offset by $6,239 used for capital expenditures.

During the three months ended September 30, 2014, net cash used in financing activities of $122,068 was for the payment of withholding taxes related to restricted stock units. During the three months ended September 30, 2013, cash used in financing activities of $31,056 consisted of the $25,215 for the payment of withholding taxes related to restricted stock units and payments of $5,841 on capital lease payments.

As of September 30, 2014, our cash and cash equivalents were $17.8 million and our current liabilities were $2.8 million, net of deferred revenue of $4.9 million. We intend to utilize existing capital resources for general corporate purposes and working capital, including advancing the Phase 3 clinical trial program with bremelanotide for FSD and preclinical and clinical development of our other product candidates and programs, including PL-3994 and MC1r and MC4r programs. Based on our current plan, we believe that the Phase 3 clinical trial program with bremelanotide will cost at least $80.0 million. The Company is preparing to initiate patient enrollment in the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless the Company has adequate funds, or commitments for adequate funds, to complete the Phase 3 clinical trials. We intend to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide, public or private equity or debt financings, or other sources.

Management believes that the Company’s existing capital resources will be adequate to fund its planned operations through the quarter ending December 31, 2015, not including initiation of its pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials.

We anticipate incurring additional losses over at least the next few years. To achieve profitability, if ever, we, alone or with others, must successfully develop and commercialize our technologies and proposed products, conduct preclinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and we do not know whether we will be able to achieve profitability on a sustained basis, if at all.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required to be provided by smaller reporting companies.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2013. There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We may be involved, from time to time, in various claims and legal proceedings arising in the ordinary course of our business. We are not currently a party to any claim or legal proceeding.

Item 1A. Risk Factors.

Risks Relating to Our Financial Results and Need for Financing

We have incurred substantial losses and expect to continue to incur substantial losses over the next few years and we may never become profitable.

We have never been profitable and we may never become profitable. As of September 30, 2014, we had an accumulated deficit of $273.2 million. We expect to incur additional losses as we continue our development of bremelanotide, PL-3994 and other product candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

Since 2005 we have not had any products available for commercial sale and have received no revenues from the sale of our product candidates. For the foreseeable future, we will have to fund all of our operations and capital expenditures from contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all. Unless and until we receive approval from the United States Food and Drug Administration, or FDA, or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. We have devoted substantially all of our efforts to research and development, including preclinical and clinical trials. Because of the numerous risks associated with developing drugs, we are unable to predict the extent of future losses, whether or when any of our product candidates will become commercially available, or when we will become profitable, if at all.

We have a limited operating history upon which to base an investment decision.

Our operations are primarily focused on acquiring, developing and securing our proprietary technology, conducting preclinical and clinical studies and formulating and manufacturing on a small-scale basis our principal product candidates. These operations provide a limited basis for stockholders to assess our ability to commercialize our product candidates.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our current product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

continuing to conduct preclinical development and clinical trials;

- participating in regulatory approval processes;

formulating and manufacturing products, or having third parties formulate and manufacture products;

post-approval monitoring and surveillance of our products;

conducting sales and marketing activities, either alone or with a partner; and

obtaining additional capital.

If we are unable to obtain regulatory approval of any of our product candidates, to successfully commercialize any products for which we receive regulatory approval or to obtain additional capital, we may not be able to recover our investment in our development efforts.

The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

the ability to raise additional capital on acceptable terms, or at all;

timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;

whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;

acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;

our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates;

the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;

the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;

the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with GMP;

a continued acceptable safety profile and efficacy during clinical development and following approval of our product candidates or any future product candidates;

our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;

acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;

our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;

our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and

our ability to in-license or acquire additional product candidates or commercial-stage products that we believe can be successfully developed and commercialized.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

We will need additional financing, including financing to submit required regulatory applications to the FDA for bremelanotide for FSD and to complete clinical trials for our other product candidates, which may be difficult to obtain.

As of September 30, 2014, we had cash and cash equivalents of $17.8 million, with current liabilities of $2.8 million net of unearned revenues of $4.9 million. We believe we have sufficient currently available working capital to fund our planned operations through the quarter ending December 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials. We will also need additional funding to

complete required clinical trials for our other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required regulatory applications to the FDA.

We are preparing to initiate Phase 3 clinical trials of bremelanotide for FSD, and intend to start patient enrollment in the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials. We estimate that the Phase 3 program, including regulatory filings for product approval, will cost at least $80.0 million. We will seek funds to support the Phase 3 program through collaborative arrangements on bremelanotide in addition to our agreement with Gedeon Richter, including marketing and distribution partnering agreements, public or private equity or debt financings, and other sources, but such additional funding may not be available on acceptable terms, or at all.

We do not have any source of significant recurring revenue and must depend on financing or partnering to sustain our operations. We may raise additional funds through public or private equity or debt financings, collaborative arrangements on our product candidates, or other sources. However, additional funding may not be available on acceptable terms, or at all. To obtain additional funding, we may need to enter into arrangements that require us to develop only certain of our product candidates or relinquish rights to certain technologies, product candidates and/or potential markets.

If we are unable to raise sufficient additional funds when needed, we may be required to curtail operations significantly, cease clinical trials and decrease staffing levels. We may seek to license, sell or otherwise dispose of our product candidates, technologies and contractual rights on the best possible terms available. Even if we are able to license, sell or otherwise dispose of our product candidates, technologies and contractual rights, it is likely to be on unfavorable terms and for less value than if we had the financial resources to develop or otherwise advance our product candidates, technologies and contractual rights ourselves.

Our future capital requirements depend on many factors, including:

the results of our Phase 3 clinical trials for bremelanotide for FSD;

the timing of, and the costs involved in, obtaining regulatory approvals for bremelanotide for FSD and our other product candidates;

the number and characteristics of any additional product candidates we develop or acquire;

the scope, progress, results and costs of researching and developing bremelanotide for FSD, PL-3994 or any future product candidates, and conducting preclinical and clinical trials;

the cost of commercialization activities if bremelanotide for FSD, PL-3994 or any future product candidates are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing bremelanotide for FSD, PL-3994 or any future product candidates and any products we successfully commercialize and maintaining our related facilities;

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the terms and timing of such arrangements;

the degree and rate of market acceptance of any future approved products;

the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;

any product liability or other lawsuits related to our products;

the expenses needed to attract and retain skilled personnel;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Raising additional capital may cause dilution to existing shareholders, restrict our operations or require us to relinquish rights.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing shareholders' ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a shareholder. Debt

financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to Our Business, Strategy and Industry

We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate, bremelanotide for FSD, which is in Phase 3 clinical development. We cannot be certain that we will be able to obtain regulatory approval for or successfully commercialize any of our product candidates.

To date, we have invested most of our efforts and financial resources in the research and development of bremelanotide for FSD, which is currently our lead product candidate. We are currently in Phase 3 clinical development in the United States for bremelanotide for FSD. Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of bremelanotide for FSD, as well as any future product candidates. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

timely completion of, or need to conduct additional, clinical trials, including our Phase 3 clinical trials in the United States for bremelanotide for FSD, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third-party contractors;

our ability to demonstrate to the satisfaction of the FDA the safety and efficacy of bremelanotide for FSD or any future product candidates through clinical trials;

whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of bremelanotide for FSD or any future product candidates;

the acceptance of parameters for regulatory approval, including our proposed indication, primary endpoint assessment and primary endpoint measurement, relating to our lead indications of bremelanotide for FSD;

our success in educating physicians and patients about the benefits, administration and use of bremelanotide for FSD or any future product candidates, if approved;

the prevalence and severity of adverse events experienced with bremelanotide for FSD or any future product candidates or approved products;

the adequacy and regulatory compliance of the autoinjector device, supplied by an unaffiliated third party, to be used as part of our bremelanotide combination product;

the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

our ability to raise additional capital on acceptable terms to achieve our goals;

achieving and maintaining compliance with all regulatory requirements applicable to bremelanotide for FSD or any future product candidates or approved products;

the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;

the effectiveness of our own or our future potential strategic collaborators' marketing, sales and distribution strategy and operations;

our ability to manufacture clinical trial supplies of bremelanotide for FSD or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or GMP;

our ability to successfully commercialize bremelanotide for FSD or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;

our ability to enforce our intellectual property rights in and to bremelanotide for FSD or any future product candidates;

our ability to avoid third-party patent interference or intellectual property infringement claims;

acceptance of bremelanotide for FSD or any future product candidates, if approved, as safe and effective by patients and the medical community; and

a continued acceptable safety profile and efficacy of bremelanotide for FSD or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of bremelanotide for FSD or any future product candidate to continue our business.

Our product candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop and test our product candidates, we will not be successful.

Our product candidates are at various stages of research and development, will require regulatory approval, and may never be successfully developed or commercialized. Our product candidates will require significant further research, development and testing before we can seek regulatory approval to market and sell them. We must demonstrate that our product candidates are safe and effective for use in patients in order to receive regulatory approval for commercial sale. Preclinical studies in animals, using various doses and formulations, must be performed before we can begin human clinical trials. Even if we obtain favorable results in the preclinical studies, the results in humans may be different. Numerous small-scale human clinical trials may be necessary to obtain initial data on a product candidate's safety and efficacy in humans before advancing to large scale human clinical trials. We face the risk that the results of our trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. Adverse or inconclusive results could delay the progress of our development programs and may prevent us from filing for regulatory approval of our product candidates. Additional factors that could inhibit the successful development of our product candidates include:

- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- failure to design appropriate clinical trial protocols;
- uncertainty regarding proper dosing;
- inability to develop or obtain a supplier for an autoinjector device that meets the FDA's medical device requirements;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- inability to add a sufficient number of clinical trial sites; or
- the availability of sufficient capital to sustain operations and clinical trials.

You should evaluate us in light of these uncertainties, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, as well as unanticipated problems and additional costs relating to:

- product approval or clearance;
- regulatory compliance;
- good manufacturing practices;
- intellectual property rights;
- product introduction; and
- marketing and competition.

If clinical trials for our product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We may be unable to commercialize our product candidates on a timely basis due to unexpected delays in our human clinical trials. Potential delaying events include:

discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;

slower than expected rates of subject recruitment and enrollment rates in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, or clinical trials for indications for which patients do not as commonly seek treatment;

difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;

difficulty in obtaining institutional review board, or IRB, approval for studies to be conducted at each site;

delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;

inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;

changes in applicable laws, regulations and regulatory policies;

delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations, or CROs, clinical trial sites and other third-party contractors;

failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;

failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug, medical device and biologic products;

delays in the scheduling and performance by the FDA of required inspections of us, our CROs, our suppliers, or our clinical trial sites, and violations of law or regulations by discovered in the course of FDA inspections;

scheduling conflicts with participating clinicians and clinical institutions; or

difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.

Any of these events or other delaying events, individually or in the aggregate, could delay the commercialization of our product candidates and have a material adverse effect on our business, results of operations and financial condition.

Even if our product candidates receive regulatory approval, they may never achieve market acceptance, in which case our business, financial condition and results of operation will be materially adversely affected.

Regulatory approval for the marketing and sale of any of our product candidates does not assure the product's commercial success. Any approved product will compete with other products manufactured and marketed by major pharmaceutical and other biotechnology companies. If any of our product candidates are approved by the FDA and do not achieve adequate market acceptance, our business, financial condition and results of operations will be materially adversely affected. The degree of market acceptance of any such product will depend on a number of factors, including:

perceptions by members of the healthcare community, including physicians, about its safety and effectiveness;

cost-effectiveness relative to competing products and technologies;

availability of reimbursement for our products from third-party payers such as health insurers, health maintenance organizations and government programs such as Medicare and Medicaid; and

advantages over alternative treatment methods.

There are currently no FDA approved products for treatment of FSD. As a result, the actual market size and market dynamics are unknown, and there is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. While we believe that an on-demand drug for FSD has competitive advantages compared to chronic or daily use hormones and other drugs, we may not be able to realize this perceived advantage in the market. Bremelanotide is administered by subcutaneous injection. While the single-use, disposable autoinjector format is designed to maximize market acceptability, bremelanotide as a subcutaneous injectable drug for FSD may never achieve significant market acceptance. In addition, we believe reimbursement of bremelanotide from third-party payers such as health insurers, HMOs or other third-party payers of healthcare costs will be limited, and that the ultimate user will pay all or a substantial part of the cost of bremelanotide for FSD. If the market opportunity

for bremelanotide is smaller than we anticipate, it may also be difficult for us to find marketing partners and, as a result, we may be unable to generate revenue and business from bremelanotide. If bremelanotide for FSD does not achieve adequate market acceptance at an acceptable price point, our business, financial condition and results of operations will be materially adversely affected.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setbacks in obtaining such approval would impair our ability to develop foreign markets for our product candidates and may have a material adverse effect on our results of operations and financial condition.

If side effects emerge that can be linked to our product candidates that are in development or after they are approved and on the market, we may be required to perform lengthy additional clinical trials, change the labeling of any such products, or withdraw such products from the market, any of which would hinder or preclude our ability to generate revenues.

If we identify side effects or other problems occur in future clinical trials, we may be required to terminate or delay clinical development of the product candidate. Furthermore, even if any of our product candidates receive marketing approval, as greater numbers of patients use a drug following its approval, if the incidence of side effects increases or if other problems are observed after approval that were not seen or anticipated during pre-approval clinical trials, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw their approval of the product;

we may be required to reformulate such products or change the way the product is manufactured;

we may become the target of lawsuits, including class action suits; and

our reputation in the market place may suffer resulting in a significant drop in the sales of such products.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

The number of subjects in our study pools in our clinical trials may be deemed by regulators to be too small.

Our clinical trials have been conducted on a pool of subjects that is structured for such research. Nevertheless, there is the possibility that for statistical reasons, the pool of subjects may be determined by the FDA or another regulatory body to be too small to verify statistical significance. In such a case, the conclusions from the previous trials will need to be established with at least another set of clinical trials testing the relevant issue.

We may not be able to keep up with the rapid technological change in the biotechnology and pharmaceutical industries, which could make any future approved products obsolete and reduce our revenue.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. In addition, any future products that we develop, including our clinical product candidates, may become obsolete before we recover expenses incurred in developing those products, which may require that we raise additional funds to continue our operations.

Competing products and technologies may make our proposed products noncompetitive.

There are other products being developed for FSD, including flibanserin, a daily-use oral drug being developed for hypoactive sexual desire disorder, and a number of oral combination drugs and daily-use oral and patch drugs incorporating testosterone. There is competition to develop drugs for treatment of FSD in both premenopausal and postmenopausal patients. Our bremelanotide drug product is intended to be administered by subcutaneous injection, and an on-demand drug product for the same indication which utilizes another route of administration, such as a conventional oral drug product, may make subcutaneous bremelanotide noncompetitive.

There are three oral FDA-approved PDE-5 inhibitor drugs for the treatment of erectile dysfunction, or ED, other approved products and devices for ED, and other products in development for treatment of ED, including products in clinical trials.

There is competition to develop drugs for ED in patients non-responsive to PDE-5 inhibitor drugs, and to develop drugs for treatment of FSD.

There are several products approved for use in treatment of obesity and related indications, and a number of other products being developed for treatment of obesity, including products in clinical trials. There is intense competition to develop drugs for treatment of obesity and related indications.

There are a number of products approved for use in treating inflammatory diseases and dermatologic indication, and other products being developed, including products in clinical trials.

We are aware of one recombinant natriuretic peptide product for acutely decompensated congestive heart failure approved and marketed in the United States, and another recombinant natriuretic peptide product approved and marketed in Japan. Clinical trials on other natriuretic peptide products are being conducted in the United States. In addition, other products for treatment of heart failure are either currently being marketed or in development, including a combination drug which increases active levels of the neuropeptide hormone atrial natriuretic peptide, or ANP.

There are numerous products approved for use in treatment of asthma, and a number of other products being developed for treatment of acute exacerbations of asthma, including products in clinical trials. There is intense competition to develop drugs for treatment of acute exacerbations of asthma.

The biopharmaceutical industry is highly competitive. We are likely to encounter significant competition with respect to bremelanotide, other melanocortin receptor agonist compounds and PL-3994. Most of our competitors have substantially greater financial and technological resources than we do. Many of them also have significantly greater experience in research and development, marketing, distribution and sales than we do. Accordingly, our competitors may succeed in developing, marketing, distributing and selling products and underlying technologies more rapidly than we can. These competitive products or technologies may be more effective and useful or less costly than bremelanotide, other melanocortin receptor agonist compounds or PL-3994. In addition, academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and may develop competing products or technologies on their own or through strategic alliances or collaborative arrangements.

We rely on third parties over whom we have no control to conduct clinical trials for our product candidates and their failure to timely perform their obligations could significantly harm our product development.

We have limited research or development staff and do not have dedicated research or development facilities. We rely on third parties and independent contractors such as researchers at CROs and universities in certain areas that are particularly relevant to our research and product development plans. We engage such researchers to conduct our preclinical studies, clinical trials and associated tests. These outside contractors are not our employees and may terminate their engagements with us at any time. In addition, we have limited control over the resources that these contractors devote to our programs and they may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. There is also competition for these relationships, and we may not be able to maintain our relationships with our contractors on acceptable terms. If our third-party contractors do not carry out their duties under their agreements with us, fail to inform us if our clinical trials fail to comply with clinical trial protocols or fail to meet expected deadlines, our ability to develop our product candidates and obtain regulatory approval on a timely basis, if at all, may be materially adversely affected.

Production and supply of our product candidates depend on contract manufacturers over whom we have no control.

We do not have the facilities to manufacture bremelanotide, the autoinjector component of our bremelanotide combination product, PL-3994, PL-8177, other melanocortin receptor agonist compounds or our other potential products. Our contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. Our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including FDA regulations concerning GMPs. Failure of third-party manufacturers to comply with GMPs, medical device quality systems regulations, or QSR, or other FDA requirements may result in enforcement action by the FDA. Failure to conduct their activities in compliance with FDA regulations could delay our development programs or negatively impact our ability to receive FDA approval of our potential products or continue marketing if they are approved. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

Use of third-party manufacturers may increase the risk that we will not have adequate suppliers of our product candidates or products.

Reliance on third-party manufacturers entails risk, to which we would not be subject if we manufactured product candidates or products ourselves, including:

reliance on the third party for regulatory compliance and quality assurance;

the possible breach of the manufacturing agreement by the third party because of factors beyond our control;

the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and

drug product supplies not meeting the requisite requirements for clinical trial use.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities.

We have no experience in marketing, distributing and selling products and will substantially rely on our marketing partners to provide these capabilities.

We do not have marketing partners for any of our products, including bremelanotide and PL-3994, except that Gedeon Richter is expected to market, or be responsible for marketing, bremelanotide for FSD in Europe and selected other territories. If any of these products are approved by the FDA or other regulatory authorities, we must either develop marketing, distribution and selling capacity and expertise, which will be costly and time consuming, or enter into agreements with other companies to provide these capabilities. We may not be able to enter into suitable agreements on acceptable terms, if at all.

If we are unable to establish sales and marketing capabilities or enter into and maintain agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.

We do not currently have an organization nor have any experience in sales, marketing and distribution of pharmaceutical products. We will need to establish sales and marketing capabilities or establish and maintain agreements with third parties to market and sell our product candidates. In order to market any products that may be approved by the FDA or similar foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities, license to a commercial partner, or make arrangements with third parties to perform these services. There are risks involved with entering into arrangements with third parties to perform these services, which could delay the commercialization of any of our product candidates, if approved for commercial sale. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and our business would suffer. In addition, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we could market and sell any products that we develop ourselves.

We do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.

Under our license, co-development and commercialization agreement with Gedeon Richter for bremelanotide for FSD in a licensed territory, we have limited control over development activities, including regulatory approvals, and no direct control over commercialization efforts. Gedeon Richter may abandon further development of bremelanotide in its licensed territory, including terminating the agreement, for any reason, including a change of priorities within Gedeon Richter or lack of success in clinical trials necessary for obtaining regulatory approvals. Because the potential value of the license arrangement with Gedeon Richter is contingent upon the successful development and commercialization of bremelanotide for FSD in the licensed territory, the ultimate value of this license will depend on the efforts of Gedeon Richter. If Gedeon Richter does not succeed in obtaining regulatory approval of bremelanotide for FSD in the licensed territory for any reason, or does not succeed in securing market acceptance of bremelanotide for FSD in the territory, or elects for any reason to discontinue development of bremelanotide for FSD, we may be unable to realize the potential value of this arrangement.

Under our research collaboration and license agreement with AstraZeneca for melanocortin-based therapeutic compounds for obesity, diabetes and related metabolic syndrome, we have no direct control over the development of compounds and have only limited, if any, input on the direction of development efforts. Based on a serious adverse event, AstraZeneca has decided to discontinue development of AZD2820, a subcutaneously administered peptide melanocortin-4 receptor partial agonist developed during their research collaboration with us. AstraZeneca may decide to abandon further development of this program, including terminating the agreement, if the results of further development efforts are negative or inconclusive, or if priorities within AstraZeneca change, or for any reason. Because the potential value of the license arrangement with AstraZeneca is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of this license will depend on the

efforts of AstraZeneca. If AstraZeneca does not succeed in developing the licensed technology for any reason, or elects for any reason to discontinue the development of this program, we will be unable to realize the potential value of this arrangement.

Our ability to achieve revenues from the sale of our products in development will depend, in part, on our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers.

Our ability to successfully commercialize our products in development will depend, in significant part, on the extent to which we or our marketing partners can obtain reimbursement for our products and also reimbursement at appropriate levels for the cost of our products. Obtaining reimbursement from governmental payers, insurance companies, HMOs and other third-party payers of healthcare costs is a time-consuming and expensive process. There is no guarantee that our products will ultimately be reimbursed. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology and third-party reimbursement might not be available for our proposed products once approved, or if obtained, might not be adequate.

There are no approved products for treating FSD, and thus there is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. Based on third-party reimbursement for approved products treating ED, we believe bremelanotide for FSD will be classified as a Tier 3 drug, so that reimbursement will be limited for bremelanotide for treatment of FSD, assuming the product is approved by the FDA. If we are able to obtain reimbursement, continuing efforts by governmental and third-party payers to contain or reduce costs of healthcare may adversely affect our future revenues and ability to achieve profitability. Third-party payers are increasingly challenging the prices charged for diagnostic and therapeutic products and related services. Reimbursement from governmental payers is subject to statutory and regulatory changes, retroactive rate adjustments, administrative rulings and other policy changes, all of which could materially decrease the range of products for which we are reimbursed or the rates of reimbursement by government payers. In addition, recent legislation reforming the healthcare system may result in lower prices or the actual inability of prospective customers to purchase our products in development. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially and adversely affect our ability to operate profitably. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment, which would have a material adverse effect on our business, financial condition and results of operations.

Even if we receive regulatory approval for our products in Europe, we may not be able to secure adequate pricing and reimbursement in Europe for us or any strategic partner to achieve profitability.

Even if one or more of our products are approved in Europe, we may be unable to obtain appropriate pricing and reimbursement for such products. In most European markets, demand levels for healthcare in general and for pharmaceuticals in particular are principally regulated by national governments. Therefore, pricing and reimbursement for our products will have to be negotiated on a "Member State by Member State" basis according to national rules, as there does not exist a centralized European process. As each Member State has its own national rules governing pricing control and reimbursement policy for pharmaceuticals, there are likely to be uncertainties attaching to the review process, and the level of reimbursement that national governments are prepared to accept. In the current economic environment, governments and private payers or insurers are increasingly looking to contain healthcare costs, including costs on drug therapies. If we are unable to obtain adequate pricing and reimbursement for our products in Europe, we or a potential strategic partner or collaborator may not be able to cover the costs necessary to manufacture, market and sell the product, limiting or preventing our ability to achieve profitability.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entails an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products or cease clinical trials. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently carry liability insurance as to certain clinical trial risks. We, or any corporate collaborators, may not in the future be able to obtain insurance at a reasonable cost or in sufficient amounts, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medi-Cal or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could have a material adverse effect on our business, results of operations and financial condition.

We are highly dependent on our management team, senior staff professionals and third-party contractors and consultants, and the loss of their services could materially adversely affect our business.

We rely on our relatively small management team and staff as well as various contractors and consultants to provide critical services. Our ability to execute our clinical programs for bremelanotide and PL-3994 and our preclinical programs for MC1r and MC4r peptide drug candidates depends on our continued retention and motivation of our management and senior staff professionals, including executive officers and senior members of product development and management who possess significant technical expertise and experience and oversee our development programs. If we lose the services of existing key personnel, our development programs could be adversely affected if suitable replacement personnel are not recruited quickly. Our success also depends on our ability to develop and maintain relationships with contractors, consultants and scientific advisors.

There is competition for qualified personnel, contractors and consultants in the pharmaceutical industry, which makes it difficult to attract and retain the qualified personnel, contractors and consultants necessary for the development and growth of our business. Our failure to attract and retain such personnel, contractors and consultants could have a material adverse effect on our business, results of operations and financial condition.

We will need to hire additional employees in order to commercialize our product candidates in the future. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.

In order to commercialize our product candidates in the future, we will need to hire experienced sales and marketing personnel to sell and market those product candidates we decide to commercialize, and we will need to expand the number of our managerial, operational, financial and other employees to support commercialization. Competition exists for qualified personnel in the biopharmaceutical field.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our business, results of operations and financial condition could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for FSD may be particularly vulnerable to unfavorable economic conditions. We do not expect bremelanotide for the treatment of FSD to be substantially reimbursed by any government or third-party payer and, as a result, demand for this product will be tied to discretionary spending levels of our targeted patient population. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for bremelanotide for FSD or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks Related to Government Regulation

Both before and after marketing approval, our product candidates are subject to ongoing regulatory requirements and, if we fail to comply with these continuing requirements, we could be subject to a variety of sanctions and the sale of any approved commercial products could be suspended.

Both before and after regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising and promotion and record keeping related to the product candidates are subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

restrictions on the products or manufacturing process;

warning letters;

civil or criminal penalties;

fines;

injunctions;

imposition of a Corporate Integrity Agreement, or CIA, requiring heightened monitoring of our compliance functions, overseen by outside monitors, and enhanced reporting requirements to, and oversight by, the FDA and other government agencies;

product seizures or detentions and related publicity requirements;

suspension or withdrawal of regulatory approvals;

regulators or IRBs may not authorize us or any potential future collaborators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new product candidates.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in the regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the marketplace. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

In addition, varying interpretations of the data obtained for preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Even if we submit an application to the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development in the near future, if at all. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or any potential future collaborators from commercializing these product candidates in the United States or other countries.

We may not be able to obtain regulatory approval of bremelanotide for FSD even if the product is effective in treating FSD.

Clinical drug development programs for our product candidates are very expensive, time-consuming, difficult to design and implement and their outcome is inherently uncertain. Approval of bremelanotide for treatment of FSD in premenopausal women requires a determination by the FDA that the product is both safe and effective. Our Phase 2B clinical trials for FSD demonstrated an acceptable safety profile and, at selected doses, statistically significant efficacy. However, the FDA may ultimately disagree with our definition of efficacy in FSD, our clinical trial designs, or our interpretation of our clinical trial results. Moreover, results obtained in Phase 3 clinical trials may be inconsistent with results obtained in our Phase 2B trials, and may demonstrate either an unacceptable safety profile or insufficient efficacy. It is also possible that safety or efficacy results obtained in Phase 3 clinical trials will be inconclusive. It is not possible to predict, with any assurance, whether the FDA will approve bremelanotide for any indications. The FDA may deny or delay approval of any application for bremelanotide if the FDA determines that the clinical data do not adequately establish the safety of the drug even if efficacy is established. If FDA approves bremelanotide, the approved labeling of the product may be limited or restricted in such ways as to inhibit or prevent the successful market acceptance and profitability of the product. Bremelanotide could take a significantly longer time to obtain approval than we expect and it may never gain approval. If regulatory approval of bremelanotide is delayed, limited or never obtained, our business, financial condition and results of operations would be materially adversely affected.

The regulatory approval process is lengthy, expensive and uncertain, and may prevent us from obtaining the approvals that we require.

Government authorities in the United States and other countries extensively regulate the advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation in the United States by the FDA and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before a new drug may be marketed in the United States include:

completion of non-clinical tests including preclinical laboratory and formulation studies and animal testing and toxicology;

submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before clinical trials may begin, and which may be placed on "clinical hold" by the FDA, meaning the trial may not commence, or must be suspended or terminated prior to completion;

performance of adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug for each proposed indication, and potentially post-approval or Phase 4 studies to further define the drug's efficacy and safety, generally or in specific patient populations;

submission to the FDA of a New Drug Application, or NDA, that must be accompanied by a substantial "user fee" payment;

FDA review and approval of the NDA before any commercial marketing or sale; and

compliance with post-approval commitments and requirements.

Satisfaction of FDA pre-market approval requirements for new drugs typically takes a number of years and the actual time required for approval may vary substantially based upon the type, complexity and novelty of the product or disease to be treated by the drug. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information, demonstrating compliance with applicable GMP requirements. Once the submission has been accepted for filing, the FDA generally has ten months to review the application and respond to the applicant. Such response may be an approval, or may be a "complete response letter" outlining additional data or steps that must be completed prior to further FDA review of the NDA. The review process is often significantly extended by FDA requests for additional information or clarification. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical trials is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of the advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. Therefore, our proposed products could take a significantly longer time than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our business, financial condition and results of operations would be materially adversely affected.

Some of our products or product candidates, including bremelanotide, may be used in combination with a drug delivery device, such as an injector or other delivery system. Medical products containing a combination of new drugs, biological products or medical devices are regulated as "combination products" in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory

categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. Our product candidates intended for use with such devices, or expanded indications that we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, because these drug delivery devices are provided by single source unaffiliated third-party companies, we are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices, maintain their own regulatory compliance, and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. We are also dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices, and maintain compliance with all regulatory requirements, could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved by the FDA. Once approved, the FDA may withdraw the product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the approved products in a specific subset of patients or a larger number of patients than were required for product approval and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to seek injunctions, levy fines and civil penalties, criminal prosecution, withdraw approvals and seize products or request recalls.

If regulatory approval of any of our product candidates is granted, it will be limited to certain disease states or conditions, patient populations, duration or frequency of use, and will be subject to other conditions as set forth in the FDA-approved labeling. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Outside the United States, our ability to market our product candidates will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process generally includes all of the risks associated with FDA approval described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product to more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficiency has been presented, a marketing authorization will be granted. If we do not obtain, or experience difficulties in obtaining, such marketing authorizations, our business, financial condition and results of operations may be materially adversely affected.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of bremelanotide for FSD or any future product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress, and court decisions are issued, that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of bremelanotide for FSD or any future product candidates. We cannot determine what effect changes in regulations, statutes, court decisions, legal interpretation or policies, when and if promulgated, enacted, issued or adopted may have on our business in the future. Such changes could, among other things:

require changes to manufacturing methods;

require recall, replacement or discontinuance of one or more of our products;

require additional recordkeeping;

limit or restrict our ability to engage in certain types of marketing or promotional activities;

alter or eliminate the scope or terms of any currently available regulatory exclusivities; and

restrict or eliminate our ability to settle any patent litigation we may bring against potential generic competitors.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

Changes in healthcare policy could adversely affect our business.

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drugs purchased by Medicare beneficiaries and introduced new reimbursement methodologies. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. We do not know what impact the MMA and similar laws will have on the availability of coverage for and the price that we receive for any approved products. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare policies in setting their own reimbursement policies, and any reduction in reimbursement that results from the MMA may result in similar reductions by private payers.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, together the Affordable Care Act or ACA. This law is expected to result in an increase in the number of people who are covered by both public and private insurance and is also expected to substantially change the way health care is financed by both government health program and private insurers, and significantly impact the pharmaceutical industry. The ACA contains a number of provisions that may impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the ACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of any products that we develop. Moreover, the ACA established a 2.3% medical device excise tax on certain transactions, including many United States sales of medical devices, which currently includes, and we expect will continue to include, United States sales of drug/device combination products. In addition, as part of the ACA’s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the “donut hole”), we will be required to provide a 50% discount on any branded prescription drugs that we develop sold to beneficiaries who fall within the donut hole. While it is too early to predict all of the specific effects the ACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

The availability of government reimbursement for prescription drugs is also likely to be impacted by the Budget Control Act of 2011, which was signed into law on August 2, 2011. This law is expected to result in federal spending cuts totaling between $1.2 trillion and $1.5 trillion over the next decade over half of which will include cuts in Medicare and other health related spending.

Risks Related to Our Intellectual Property

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and
- whether we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the United States Patent and Trademark Office, or USPTO, may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

If we are unable to keep our trade secrets confidential, our technologies and other proprietary information may be used by others to compete against us.

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws and agreements with our employees and other persons who have access to our proprietary information. These agreements and arrangements may not provide meaningful protection for our proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

Risks Relating to Obligations in Our 2012 Private Placement

Under agreements relating to our 2012 private placement, we are required to allow purchasers in the 2012 private placement to participate in certain future equity and debt financings, which may restrict our ability to raise funds on acceptable terms, or at all.

For six years after our 2012 private placement, unless the purchasers own less than 20% of our outstanding common stock calculated as if the warrants were exercised, the purchasers have the right of first negotiation on any subsequent equity or debt financing. If we do not agree to terms of a financing with them, and negotiate with a third party on a financing, we must offer to sell to the purchasers at least 55% of the financing, and the purchasers may elect to purchase all or a portion of the financing. We will require significant additional resources and capital for our Phase 3 bremelanotide clinical trial program and other clinical trial programs. The right of first negotiation and right of participation granted to the purchasers in our 2012 private placement may make it more difficult to raise additional funding through public or private equity or debt financings or other sources. Such funding may not be available on acceptable terms, or at all.

Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to redeem Series A 2012 and Series B 2012 warrants at the option of the holders in the event of any takeover, change of control or other fundamental transaction which we permit.

Under the purchase agreement and form of warrants for our 2012 private placement, if we permit, make or allow a takeover, change of control or other fundamental transaction, including any transfer of all or substantially all of our properties or assets, then so long as any warrants remain outstanding we are required, as elected by the warrant holders, to pay such holders a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person. The application of these provisions could adversely affect our financial position and have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition or change of control more costly.

Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to oppose any takeover or change of control that does not provide specified rights to holders of Series A 2012 and Series B 2012 warrants.

Under the purchase agreement and form of warrants for our 2012 private placement, so long as any warrants remain outstanding we are required to (i) not permit, (ii) take necessary action to prevent both the occurrence or consummation of, and (iii) not be a party to any fundamental transaction, change of control or similar event unless contractually-specified rights are provided with respect to payment of a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person.

We are also required, subject to the exercise by our board of its fiduciary duties, to take all reasonable efforts to adopt a poison pill or any other anti-takeover provision or method necessary to prevent the fundamental transaction, change of control or similar event. The application of these provisions could have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition or change of control more costly.

Risks Related to the Ownership of Our Common Stock

Our stock price is volatile and may fluctuate in a way that is disproportionate to our operating performance and we expect it to remain volatile, which could limit investors’ ability to sell stock at a profit.

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

publicity regarding actual or potential clinical results relating to products under development by our competitors or us;

delay or failure in initiating, completing or analyzing preclinical or clinical trials or unsatisfactory designs or results of these trials;

interim decisions by regulatory agencies, including the FDA, as to clinical trial designs, acceptable safety profiles and the benefit/risk ratio of products under development;

achievement or rejection of regulatory approvals by our competitors or by us;

announcements of technological innovations or new commercial products by our competitors or by us;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

regulatory developments in the United States and foreign countries;

economic or other crises and other external factors;

period-to-period fluctuations in our revenue and other results of operations;

changes in financial estimates by securities analysts; and

sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues, if any, in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer further. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

For the 12-month period ended October 31, 2014, the price of our stock has been volatile, ranging from a high of $1.50 per share to a low of $0.58 per share. In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Substantial future sales of our shares of common stock in the public market, or the perception that these sales could occur, could cause the price of our common stock to decline.

Additional sales of our common stock in the public market, or the perception that these sales could occur, could cause the market price of our common stock to decline.

As a public company in the United States, we are subject to the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley. We can provide no assurance that we will, at all times, in the future be able to report that our internal controls over financial reporting are effective.

Companies that file reports with the Securities and Exchange Commission, or the SEC, including us, are subject to the requirements of Section 404 of Sarbanes-Oxley. Section 404 requires management to establish and maintain a system of internal control over financial reporting, and annual reports on Form 10-K filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, must contain a report from management assessing the effectiveness of a company’s internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis will be a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

As a smaller company, it may be difficult for us to attract or retain the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity of and market price of our common stock. We do not have any control of the equity research analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company, or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Holders of our preferred stock may have interests different from our common stockholders.

We are permitted under our certificate of incorporation to issue up to 10,000,000 shares of preferred stock. We can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from our common stockholders. 4,697 shares of our Series A Preferred Stock remain outstanding as of October 31, 2014. Each share of Series A Preferred Stock is convertible at any time, at the option of the holder, and such conversion could dilute the value of our common stock to current stockholders and could adversely affect the market price of our common stock. The conversion price decreases if we sell common stock (or equivalents) for a price per share less than the conversion price or less than the market price of the common stock and is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which results in an increase or decrease in the number of shares of common stock outstanding. Upon (i) liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, (ii) sale or other disposition of all or substantially all of the assets of the Company, or (iii) any consolidation, merger, combination, reorganization or other transaction in which the Company is not the surviving entity or in which the shares of common stock constituting in excess of 50% of the voting power of the Company are exchanged for or changed into other stock or securities, cash and/or any other property, after payment or provision for payment of the debts and other liabilities of the Company, the holders of Series A Preferred Stock will be entitled to receive, pro rata and in preference to the holders of any other capital stock, an amount per share equal to $100 plus accrued but unpaid dividends, if any. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation premiums and may have greater voting rights than our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.

We do not anticipate paying any cash dividends in the foreseeable future and intend to retain future earnings, if any, for the development and expansion of our business. Our outstanding Series A Preferred Stock, consisting of 4,697 shares on October 31, 2014, provides that we may not pay a dividend or make any distribution to holders of any class of stock unless we first pay a special dividend or distribution of $100 per share to the holders of the Series A Preferred Stock. In addition, the terms of existing or future agreements may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Anti-takeover provisions of Delaware law and our charter documents may make potential acquisitions more difficult and could result in the entrenchment of management.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with an “interested stockholder” for a period of three years after the date of the transaction in which the person first becomes an “interested stockholder,” unless the business combination is approved in a prescribed manner.

We are authorized to issue up to 300,000,000 shares of common stock. To the extent that we sell or otherwise issue authorized but currently unissued shares, this could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock.

Our charter authorizes us to issue up to 10,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If we exercise this right, it could be more difficult for a third party to acquire a majority of our outstanding voting stock.

In addition, our equity incentive plans generally permit us to accelerate the vesting of options and other stock rights granted under these plans in the event of a change of control. If we accelerate the vesting of options or other stock rights, this action could make an acquisition more costly.

The application of these provisions could have the effect of delaying or preventing a change of control, which could adversely affect the market price of our common stock.

As of October 31, 2014, there were 96,380,173 shares of common stock underlying outstanding convertible preferred stock, options, restricted stock units and warrants. Stockholders may experience dilution from the conversion of preferred stock, exercise of outstanding options and warrants and vesting of restricted stock units.

As of October 31, 2014, holders of our outstanding dilutive securities had the right to acquire the following amounts of underlying common stock:

- 52,829 shares of common stock reserved for issuance upon any conversion of our Series A Convertible Preferred Stock outstanding as of October 31, 2014;

- 4,229,913 shares issuable on the exercise of stock options, at exercise prices ranging from $0.60 to $37.50 per share;

845,900 shares issuable under restricted stock units which vest on dates between June 25, 2015 and June 25, 2018, subject to the fulfillment of service conditions; and

91,251,531 shares issuable on the exercise of warrants at exercise prices ranging from $0.01 to $1.50 per share outstanding as of October 31, 2014.

If the holders convert, exercise or receive these securities, or similar dilutive securities we may issue in the future, stockholders may experience dilution in the net book value of their common stock. In addition, the sale or availability for sale of the underlying shares in the marketplace could depress our stock price. We have registered or agreed to register for resale substantially all of the underlying shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, which could result in significant downward pressure on our stock price.

Our failure to meet the continued listing requirements of the NYSE MKT could result in a de-listing of our common stock.

Our common shares are listed on the NYSE MKT, a national securities exchange, under the symbol “PTN”. Although we currently meet the NYSE MKT’s listing standards, which generally mandate that we meet certain requirements relating to stockholders’ equity, market capitalization, aggregate market value of publicly held shares and distribution requirements, we cannot assure you that we will be able to continue to meet the NYSE MKT’s listing requirements. If we fail to satisfy the continued listing requirements of the NYSE MKT, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE MKT may take steps to de-list our common stock. If the NYSE MKT delists our securities for trading on its exchange, we could face significant material adverse consequences, including:

a limited availability of market quotations for our securities;

reduced liquidity with respect to our securities;

a determination that our shares of common stock are “penny stock” which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;

a limited amount of news and analyst coverage for our company; and

a decreased ability to issue additional securities or obtain additional financing in the future.

Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we may take actions to restore our compliance with the NYSE MKT’s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NYSE MKT minimum bid price requirement or prevent future non-compliance with the NYSE MKT’s listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” Our common shares are considered to be covered securities because they are listed on the NYSE MKT. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer listed on the NYSE MKT, our common stock would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Issuer purchases of equity securities. We have not and do not currently intend to retire or repurchase any of our capital securities other than providing our employees with the option to withhold shares to satisfy tax withholding amounts due from employees upon the vesting of restricted stock units in connection with our 2011 Stock Incentive Plan. The following 37,684 shares were withheld during the three-month period ended September 30, 2014 at the direction of the employees as permitted under the 2011 Stock Incentive Plan in order to pay the minimum amount of tax liability owed by the employee from the vesting of those units:

Period	Maximum

	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Number of Shares that May Yet be Purchased Under Announced Plans or Programs
July 1-31, 2014	37,684	$1.02	-	-
August 1-31, 2014	-	-	-	-
September 1-30, 2014	-	-	-	-
Total	37,684	$1.02	-	-

(1) Consists solely of 37,684 shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock units.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibits filed or furnished with this report:

Exhibit Number	Description
10.1	License, Co-Development and Commercialization Agreement, dated August 29, 2014, by and between Palatin Technologies, Inc. and Chemical Works of Gedeon Richter Plc, filed as Exhibit 27 to the Company's Form 10-K/A filed with the Securities and Exchange Commission on October 9, 2014 and incorporated herein by reference. *
31.1	Certification of Chief Executive Officer.
31.2	Certification of Chief Financial Officer.
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

*Confidential treatment has been granted for certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.

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 thereunto duly authorized.

Palatin Technologies, Inc.
(Registrant)

Date: November 14, 2014

/s/ Carl Spana
Carl Spana, Ph.D.
President and
Chief Executive Officer (Principal Executive Officer)

Date: November 14, 2014

/s/ Stephen T. Wills
Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
10.1	License, Co-Development and Commercialization Agreement, dated August 29, 2014, by and between Palatin Technologies, Inc. and Chemical Works of Gedeon Richter Plc, filed as Exhibit 27 to the Company's Form 10-K/A filed with the Securities and Exchange Commission on October 9, 2014 and incorporated herein by reference. *
31.1	Certification of Chief Executive Officer.
31.2	Certification of Chief Financial Officer.
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

*Confidential treatment has been granted for certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.