PALATIN TECHNOLOGIES INC
Form 10-K
September 13, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10 - K

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

For the fiscal year ended June 30, 2018

or

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

For the transition period from _____ to _____

Commission file number: 001-15543

PALATIN TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	95-4078884 (I.R.S. Employer Identification No.)
4B Cedar Brook Drive Cranbury, New Jersey (Address of principal executive offices)	08512 (Zip Code)

(609) 495-2200
(Registrant’s telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (December 31, 2017): $166,295,449.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (September 11, 2018): 202,048,804.

PALATIN TECHNOLOGIES, INC.

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Special Note Regarding Forward-Looking Statements

In this Annual Report on Form 10-K (this "Annual Report") references to "we," "our," "us," the "Company" or "Palatin" mean Palatin Technologies, Inc. and its subsidiary.

Statements in this Annual Report, 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 (the "Exchange Act"). The forward-looking statements in this Annual Report do not constitute guarantees of future performance. Investors are cautioned that statements that are not strictly historical facts contained in this Annual Report, including, without limitation, the following are forward looking statements:

estimates of our expenses, future revenue and capital requirements;

our ability to achieve and maintain profitability;

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 completion of required clinical trials and studies and validation of methods and controls used to manufacture Vyleesi™ (the trade name for bremelanotide) for the treatment of premenopausal women with hypoactive sexual desire disorder ("HSDD"), which is a type of female sexual dysfunction ("FSD");

our expectation regarding the timing of our regulatory submissions for approval of Vyleesi for HSDD in the United States and in certain other jurisdictions outside the United States;

our expectation regarding performance of our exclusive licensees of Vyleesi, including;

o
AMAG Pharmaceuticals, Inc. ("AMAG") for North America,

o
Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., for the territories of the People's Republic of China, Taiwan, Hong Kong S.A.R.

and Macau S.A.R. (collectively, “China”), and

o
Kwangdong Pharmaceutical Co., Ltd. (“Kwangdong”) for the Republic of Korea (“Korea”);

the potential for commercialization of Vyleesi for HSDD in North America by AMAG and other product candidates, if approved, by us;

our expectations regarding the potential market size and market acceptance for Vyleesi for HSDD 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 performance of our management team, senior staff professionals, and third-party contractors and consultants;

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 in the United States and throughout the world;

our compliance with federal and state laws and regulations;

the timing and costs associated with obtaining regulatory approval for our product candidates;

the impact of fluctuations in foreign exchange rates;

the impact of legislative or regulatory healthcare reforms in the United States;

our ability to adapt to changes in global economic conditions as well as competing products and technologies; and

our ability to remain listed on the NYSE American stock exchange.

Such forward-looking statements involve 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 under the caption “Risk Factors” and elsewhere in this Annual Report, and any of those made in our other reports filed with the U.S. Securities and Exchange Commission (the “SEC”). Except as required by law, we do not intend, and undertake no obligation, to publicly update forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

Palatin Technologies® is a registered trademark of Palatin Technologies, Inc. Vyleesi™ is a trademark of AMAG Pharmaceuticals, Inc. in North America and of Palatin Technologies, Inc. elsewhere in the world.

PART I

Item 1. Business.

Overview

We are a specialized biopharmaceutical company developing first-in-class medicines based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our most advanced product candidate is Vyleesi™, the trade name for bremelanotide, a peptide melanocortin receptor 4 (MC4r) agonist, for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder ("HSDD"), which is a type of female sexual dysfunction ("FSD"), defined as low desire with associated distress or interpersonal difficulty. A New Drug Application ("NDA") has been submitted to the U.S. Food and Drug Administration ("FDA") by our exclusive North American licensee, AMAG Pharmaceuticals, Inc. ("AMAG") and accepted for filing by the FDA, with an FDA decision on approval expected in the first quarter of calendar 2019.

Vyleesi. Vyleesi is an on demand subcutaneous injectable product for the treatment of HSDD in premenopausal women. Vyleesi is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). In March 2018, our exclusive North American licensee for Vyleesi, AMAG, submitted an NDA to the FDA for Vyleesi for the treatment of HSDD in premenopausal women, which was accepted for filing and review by the FDA. The Prescription Drug User Fee Act ("PDUFA") date for completion of FDA review of the Vyleesi NDA is March 23, 2019. We have also licensed rights to Vyleesi to Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun") for the territories of the People's Republic of China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. (collectively, "China"), and Kwangdong Pharmaceutical Co., Ltd. ("Kwangdong") for the Republic of Korea ("Korea").

Our Phase 3 studies for HSDD in premenopausal women, called the RECONNECT studies, consisted of two double-blind placebo-controlled, randomized parallel group studies comparing the on demand use of 1.75 mg of Vyleesi versus placebo, in each case, delivered via a subcutaneous auto-injector. Each trial consisted of more than 600 patients randomized in a 1:1 ratio to either the treatment arm or placebo with a 24-week evaluation period. In both clinical trials, Vyleesi met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments.

After completing the studies, patients had the option to continue in an open-label safety extension study for an additional 52 weeks. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. In the Phase 3 clinical trials, the most frequent adverse events were nausea, flushing, and headache, which were generally mild-to-moderate in intensity and were transient.

We retain worldwide rights for Vyleesi for HSDD and all other indications outside North America, Korea and China. We are actively seeking potential partners for marketing and commercialization rights for Vyleesi for HSDD outside the licensed territories. However, we may not be able to enter into suitable agreements with potential partners on acceptable terms, if at all.

Melanocortin Receptor Systems. There are five melanocortin receptors, MC1r through MC5r. Modulation of these receptors, through use of receptor-specific agonists, which activate receptor function, or receptor-specific antagonists, which block receptor function, can have significant pharmacological effects. Our new product development activities primarily focus on MC1r agonists, with potential to treat a number of inflammatory and autoimmune diseases such as dry eye disease, also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. We believe that MC1r agonists, including the MC1r agonist peptides we are developing, have broad

anti-inflammatory effects and appear to utilize mechanisms engaged by the endogenous melanocortin system in regulation of the immune system and resolution of inflammatory responses. We are also developing peptides that are active at more than one melanocortin receptor, and MC4r agonists, with potential utility in a number of obesity and metabolic-related disorders, including rare disease and orphan indications.

PL-8177, a selective MC1r agonist peptide, is our lead clinical development candidate for inflammatory bowel diseases, with potential applicability for a number of other diseases. We filed an Investigational New Drug (“IND”) application on PL-8177 in late 2017 and have completed subcutaneous dosing of human subjects in a Phase 1 single and multiple ascending dose clinical safety study, with data expected in the fourth quarter of calendar year 2018. We anticipate starting a clinical study with oral dosing of PL-8177 in human subjects in the fourth quarter of calendar year 2018, with data expected in the first half of calendar 2019.

PL-8331, a dual MC1r and MC5r peptide agonist, is a preclinical development candidate for treating ocular inflammation. We have initiated IND-enabling preclinical activities with PL-8331, and if results are favorable, anticipate filing an IND and initiating clinical trials for treatment of dry eye disease in the second half of calendar year 2019.

We have initiated preclinical programs with MC4r peptides and orally-active small molecules for treatment of rare genetic metabolic and obesity disorders, and if results are favorable, anticipate selecting a lead clinical development candidate and completing IND-enabling activities in calendar year 2019.

Natriuretic Peptide Receptor Systems. The natriuretic peptide receptor ("NPR") system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis, heart failure, acute asthma, other pulmonary diseases and hypertension. While the therapeutic potential of modulating this system is well appreciated, development of therapeutic agents has been difficult due, in part, to the short biological half-life of native peptide agonists. We have designed and are developing potential NPR candidate drugs that are selective for one or more different natriuretic peptide receptors, including natriuretic peptide receptor-A ("NPR-A"), natriuretic peptide receptor B ("NPR-B"), and natriuretic peptide receptor C ("NPR-C").

PL-3994 is an NPR-A agonist we developed which has completed Phase 1 clinical safety studies. It has potential utility in treatment of a number of cardiovascular diseases, including genetic and orphan diseases resulting from a deficiency of endogenous active NPR-A. We have ongoing academic collaborations with several institutions with PL-3994.

PL-5028, a dual NPR-A and NPR-C agonist we developed, is in preclinical development for cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis. We have ongoing academic collaborations with several institutions with PL-5028, and seek to enter into a development partnership by the end of calendar year 2019.

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

Our Strategy

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 existing license agreements, as well as any future research, collaboration or license agreements; and

Completing development and seeking regulatory approval of certain of our other product candidates.

Our Melanocortin Receptor-Specific Programs

The melanocortin system is involved in a large and diverse number of physiologic functions. We are focusing on MC1r agonists and MC4r agonists. MC1r agonists may have the potential to treat a variety of conditions and diseases, including a number of inflammatory and autoimmune diseases such as dry eye disease, uveitis, diabetic retinopathy and inflammatory bowel disease. MC4r agonists may have the potential to treat FSD, including HSDD, and a number of metabolic-related diseases, including genetic metabolic and obesity disorders.

Vyleesi for HSDD. With our exclusive North American licensee, AMAG, we are developing subcutaneously administered Vyleesi for the treatment of HSDD in premenopausal women. FSD is defined as persistent or recurring problems during one or more of the stages of sexual response with associated distress. Acquired generalized HSDD, the most common form of FSD, is characterized by low sexual desire that causes marked distress or interpersonal difficulties and is not due to coexisting medical or psychiatric conditions, relationship problems or effects of medication or other drug substances.

Vyleesi is intended to be self-administered in the thigh or abdomen on demand with a single-use subcutaneous auto-injector device before anticipated sexual activity. The treatment effects may last up to 15 hours following self-administration. Vyleesi is a melanocortin agonist with a mechanism of action which we believe involves activation of endogenous neuronal pathways in the brain regulating sexual arousal and desire responses.

Two successful RECONNECT Phase 3 studies, Studies 301 and 302, have been completed, which randomized 1,247 premenopausal women diagnosed with acquired HSDD to either placebo or Vyleesi arms. The Phase 3 studies included a 12-month open-label safety extension study.

The primary efficacy analysis population was the modified intent-to-treat patient population, consisting of 1,202 women with HSDD in the United States and Canada. Patients self-administered either 1.75 mg of Vyleesi or placebo on demand in anticipation of sexual activity. The efficacy portion of each study consisted of a 24-week treatment evaluation period.

The co-primary endpoints for the Phase 3 clinical trials were increase in sexual desire measured using the Female Sexual Function Index: Desire Domain (“FSFI-D”) and decrease in distress associated with low sexual desire measured using Female Sexual Distress Scale-Desires/Arousal/Orgasm (“FSDS-DAO”) Item 13. The FSFI-D is a validated patient reported outcome measurement tool of sexual desire in the context of overall sexual function. The FSDS-DAO Item 13 is a validated patient reported outcome measurement tool of distress related to sexual dysfunction, measuring personal distress associated with low sexual desire. Both Phase 3 Studies 301 and 302 with Vyleesi for HSDD in premenopausal women met the pre-specified co-primary efficacy endpoints.

The FSFI-D showed a statistically significant increase for Vyleesi compared to placebo in both trials in the modified intent-to-treat patient population:

Study 301: Mean change of 0.54 vs. 0.24, median change of 0.60 vs. 0.00, p=0.0002; and,

Study 302: Mean change of 0.63 vs. 0.21, median change of 0.60 vs. 0.00, p<0.0001.

The FSDS-DAO Item 13 showed a statistically significant reduction in distress related to low sexual desire for Vyleesi compared to placebo in both trials in the modified intent-to-treat patient population:

Study 301: Mean change of -0.7 vs. -0.4, median change of -1.0 vs. 0.0, p<0.0001; and,

Study 302: Mean change of -0.7 vs. -0.4, median change of -1.0 vs. 0.0, p=0.0053.

The changes seen in both co-primary endpoints were clinically significant. An independent committee evaluated the clinical significance of co-primary endpoint study results using multiple assessments of patient benefit, and was based on discussions with the FDA and FDA guidance documents.

In the safety population (1,247 patients), Vyleesi appeared to be well tolerated. The most frequent adverse events were nausea, flushing, and headache, which were generally mild-to-moderate in intensity and were transient. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label safety extension portion of the study. All of the patients in the extension study, which was completed in 2017, received Vyleesi.

In the Phase 3 clinical study program patients self-administered Vyleesi with a single-use autoinjector device, which is intended to be the commercial drug product. The autoinjector does not have a visible needle, and is expected to be stored by patients at room temperature. Women administer Vyleesi by pressing the autoinjector pen collar against either their thigh or abdomen, and the autoinjector pen automatically introduces the needle, administers the dose of Vyleesi under the skin and audibly signals when the drug had been delivered and the needle has been retracted.

With AMAG, we have conducted multiple pharmacokinetic and safety pharmacology studies, including an abuse-liability study and drug-to-drug interaction studies, as well as certain chemistry, manufacturing and controls activities, including a drug product process validation study. These studies were required in order to file an NDA with FDA.

New Drug Application and Regulatory Pathway. In March 2018, our exclusive North American licensee AMAG, submitted an NDA to FDA for Vyleesi for the treatment of HSDD in premenopausal women, which was subsequently accepted for filing and review by the FDA. The PDUFA date for completion of FDA review of the Vyleesi NDA is March 23, 2019, with an FDA Advisory Committee meeting on Vyleesi for HSDD set for early 2019. We cannot assure you that a complete review of the Phase 3 efficacy data and the pharmacokinetic and safety pharmacology studies will support approval of Vyleesi for HSDD, that the FDA Advisory Committee will make a favorable recommendation or that the FDA will approve the NDA for Vyleesi.

Medical Need — HSDD. The 2006 PRESIDE (Prevalence of Female Sexual Problems Associated with Distress and Determinants of Treatment Seeking) study, a cross-sectional, population-based survey of 31,581 female adult respondents in the United States published in 2008 in the journal Obstetrics & Gynecology, found that approximately 22% of women reported a sexual problem and 11% were women with HSDD. Based on the number of premenopausal women in the United States according to the U.S. Census, the presenting market size of premenopausal women with primary HSDD is at least 5.8 million women. Despite one FDA-approved HSDD therapy on the market today for pre-menopausal women, we believe that patient awareness and understanding of the condition is extremely low, and as a result few women currently seek treatment. HSDD may go undiagnosed due to various factors such as embarrassment or stigma, lack of awareness of low sexual desire as a medical condition or attribution to other external factors, such as stress or fatigue.

Subcutaneous Vyleesi. Vyleesi, which is believed to act through activation of melanocortin receptors in the central nervous system, is a first-in-class pharmaceutical agent in development as a treatment of HSDD. Vyleesi is intended for on demand use and is self-administered by the patient, using a simple and patient-friendly single-use autoinjector pen, prior to anticipated sexual activity.

Partnering. In January 2017, we entered into a license agreement with AMAG, pursuant to which we granted AMAG an exclusive license in all countries of North America, with the right to grant sublicenses, to research, develop and commercialize products containing Vyleesi. AMAG also has a non-exclusive license, with the right to grant sublicenses, to manufacture products containing Vyleesi in North America, and to research, develop and manufacture, but not commercialize, products containing Vyleesi in countries outside North America. Upon the license agreement becoming effective on February 2, 2017, AMAG paid us $60 million as a one-time initial payment, and has reimbursed us $25 million for direct out-of-pocket expenses incurred in development and regulatory activities necessary to file an NDA, less certain expenses directly paid or to be paid by AMAG. Upon the FDA acceptance of the Vyleesi NDA filing for HSDD, AMAG paid us $20 million less agreed deductions for expenses incurred by AMAG. In addition, we may receive $60 million upon FDA approval of Vyleesi for HSDD, and up to $300 million in sales milestone payments based on achievement of certain annual net sales amounts of products containing Vyleesi. AMAG will also pay tiered royalties on annual net sales of products containing Vyleesi at rates ranging from the high single-digits to the low double-digits.

In early September 2017, we entered into a license agreement with Fosun for exclusive rights to commercialize Vyleesi in China. We received an upfront payment of $5.0 million, less required tax withholding, and when regulatory approval for a Vyleesi product is obtained in China will receive a $7.5 million milestone payment. We may receive up to $92.5 million in sales related milestones, and will receive high single-digit to low double-digit royalties on net sales in China. In November 2017 we entered into a license agreement with Kwangdong for exclusive rights to commercialize Vyleesi in Korea, and received an upfront payment of $500,000, less required tax withholding. Upon the first commercial sale of Vyleesi in Korea we will receive a $3.0 million milestone payment and we will receive mid-single-digit to low double-digit royalties on all net sales, and may receive up to $37.5 million in sales related milestones.

We retain worldwide rights for Vyleesi for FSD, HSDD and all other indications outside North America, China and Korea. We are in active discussions with potential partners for marketing and commercialization rights for Vyleesi in other jurisdictions, including Europe. We may not be able to enter into suitable agreements with potential partners on acceptable terms, if at all.

MC1r Peptide Agonists. Our goal is to design and develop highly selective MC1r agonist peptides and dual MC1r and MC5r agonist peptides for treatment of a variety of inflammatory and autoimmune indications. In animal models our peptides, as well as the endogenous agonist alpha-MSH, can reduce inflammation and potentially resolve chronic inflammatory conditions. We believe that our agonist peptides suppress certain inflammatory cytokines, and modulate the activities of other cells, such as monocytes and T cells, to mediate immune tolerance, and may utilize mechanisms engaged by the endogenous melanocortin system in regulation of the immune system and resolution of inflammatory responses.

We have conducted preclinical animal studies with MC1r and dual MC1r and MC5r peptide drug candidates for a number of inflammatory disease and autoimmune indications. MC1r is upregulated in a number of diseases, including inflammatory bowel disease and ocular indications such as uveitis, diabetic retinopathy and dry eye disease. Work with rodent animal models have demonstrated therapeutic responses that are statistically significant compared to placebo, and that are equal to or superior to established positive controls in animal models. However, success in animal models does not necessarily mean that any of the drug candidates will be able to successfully treat any disease or condition in human patients.

Our MC1r and dual MC1r and MC5r peptide drug candidates are highly specific, with substantially greater binding and activity at MC1r, or MC1r and MC5r for dual target drug candidates, than at other melanocortin receptors. In vitro safety studies have shown that our peptide drug candidates have no activity in a wide range of receptors, ion channels and kinases.

PL-8177 Evaluation. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as our lead clinical development candidate for inflammatory bowel diseases, including ulcerative colitis. PL-8177 is a cyclic peptide comprised of seven amino acids. We may also explore use of PL-8177 for other indications or diseases.

We completed preclinical toxicology testing on PL-8177 as well as chemistry, controls and manufacturing activities to support Phase 1 studies, and filed an IND with the FDA. Pursuant to that IND, we have completed dosing in a Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose study to evaluate the safety and tolerability of PL-8177 administered via subcutaneous injection. We anticipate top line data in the fourth quarter of 2018.

We have developed an oral formulation of PL-8177, and have evaluated the oral formulation in animal models. In animal models PL-8177 was protected from degradation in the stomach and small intestine and delivered to the large intestine and colon over an extended period. In addition, orally administered PL-8177 had a significant effect on resolving inflammation in a rat bowel inflammation model. We anticipate starting a clinical study with oral dosing of PL-8177 in human subjects in the fourth quarter of calendar year 2018, with data expected in the first half of calendar 2019.

PL-8331 Evaluation. We have designated our peptide PL-8331, which is a dual MC1r and MC5r agonists, as a preclinical development candidate for treating ocular inflammatory diseases. We are conducting ongoing preclinical IND-enabling activities with PL-8331, and if results are favorable, anticipate filing an IND and initiating clinical trials for treatment of dry eye disease in the second half of calendar year 2019.

Next Generation MC4r Peptide and Small Molecule Agonists. We have developed a series of highly selective MC4r peptides and orally active small molecules. In developing these compounds, we examined effectiveness in animal models of sexual response and obesity, and also determined cardiovascular effects, primarily looking at changes in blood pressure. Results of these studies, including studies of weight loss in diet-induced obese mice and leptin-deficient mice with orally administered MC4r compounds, suggest that certain of these compounds may have significant medical and commercial potential for treatment of conditions responsive to MC4r activation, including certain orphan and rare disease indications. We are continuing preclinical development work, and evaluating the potential for orphan designation under the Orphan Drug Act.

We have initiated a chemistry development program for both MC1r and MC4r specific small molecule agonists, and will be evaluating compounds we develop in functional assays.

Our Natriuretic Peptide Receptor-Specific Programs

The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of heart failure, acute asthma, other pulmonary diseases and hypertension. While the therapeutic potential of modulating this system is well appreciated, development of therapeutic agents has been difficult due, in part, to the short biological half-life of native peptide agonists.

We have designed and are developing potential candidate drugs that are selective for different natriuretic peptide receptors, including NPR-A, NPR-B, NPR-C, and combinations of receptors.

PL-3994. PL-3994 is our lead NPR-A product candidate, and is a synthetic mimetic of the endogenous neuropeptide hormone atrial natriuretic peptide (“ANP”) and an NPR-A agonist. PL-3994 may be suitable for replacement therapy in patients with prohormone processing deficiencies characterized by insufficient endogenous ANP. PL-3994 activates NPR-A, a receptor known to play a role in cardiovascular homeostasis. Consistent with being an NPR-A agonist, PL-3994 increases plasma cyclic guanosine monophosphate (“cGMP”) levels, a pharmacological response consistent with the effects of endogenous natriuretic peptides on cardiovascular function and smooth muscle relaxation. PL-3994 also decreases activity of the renin-angiotensin-aldosterone system (“RAAS”), a hormone system that regulates blood pressure and fluid balance. The RAAS system is frequently over-activated in heart failure patients, leading to worsening of cardiovascular function.

PL-3994, our lead product development candidate which has completed Phase 1 safety studies, is one of a number of natriuretic peptide receptor agonist compounds we have developed. In conjunction with clinicians at a major research institution, PL-3994 is tentatively scheduled to enter Phase 2A clinical trials within the next twelve months. PL-3994 is a synthetic molecule incorporating a novel and proprietary amino acid mimetic structure, and has an extended circulation half-life and metabolic stability compared to endogenous ANP. Based on the half-life and pharmacokinetics, we believe that PL-3994 is amenable to once daily chronic use subcutaneous administration.

Prior Clinical Studies with PL-3994. Human clinical studies of PL-3994 commenced with a Phase 1 trial, which concluded in 2008. This was a randomized, double-blind, placebo-controlled study in 26 healthy volunteers who received either PL-3994 or a placebo subcutaneously. Dosing concluded with the successful achievement of the primary endpoint of the study, a pre-specified reduction in systemic blood pressure. No volunteer experienced a serious or severe adverse event. Elevations in plasma cGMP levels, increased diuresis and increased natriuresis were all observed for several hours after single subcutaneous doses. Later in 2008, we conducted a trial in volunteers with controlled hypertension who were receiving one or more conventional antihypertensive medications. No volunteer experienced a serious or severe adverse event. Elevations in plasma cGMP levels were observed for several hours after single subcutaneous doses. Based on the studies to date, PL-3994 is ready for Phase 2 safety and efficacy studies.

PL-5028. We are in preclinical development with PL-5028, a dual natriuretic peptide receptor A and C agonist we developed, for cardiovascular disease indications, including reducing cardiac hypertrophy and fibrosis. Depending on results of preclinical studies, we may file an IND application in the first half of calendar year 2019, and thereafter initiate a Phase 1 clinical safety study.

Administration of PL-3994 and PL-5028. For heart failure and other cardiovascular disease indications we believe that subcutaneous administration may be employed. In studies to date, PL-3994 is well absorbed through the subcutaneous route of administration. In human studies with PL-3994, the pharmacokinetic and pharmacodynamic half-lives were on the order of hours, significantly longer than the comparable half-lives of endogenous natriuretic peptides. We believe that subcutaneous PL-3994 or PL-5028, if successful, will be appropriate for self-administration by patients, similar to insulin and other self-administered drugs.

Heart Failure and Cardiovascular Disease Indications. Patient populations have been identified which have reduced levels of endogenous active natriuretic peptides, including endogenous active ANP. The reduced levels have a variety of causes, including mutations in endogenous natriuretic peptides and in enzymes necessary to convert natriuretic peptide sequences to their active form. Patients with reduced levels of endogenous active natriuretic peptides are reported to have a poor response to current drug therapies and to have increased rates of cardiac remodeling and cardiac events.

We believe that our natriuretic peptide potential candidate drugs have the potential to treat heart failure with preserved ejection fraction (“HFpEF”), which is a high unmet medical need with no approved treatment options, heart failure with reduced ejection fraction (“HFrEF”), and patients with reduced levels of endogenous active natriuretic peptides, such as corin deficiencies, which is a high unmet medical need in patients with a poor response to current therapies, with the objective to restore normal natriuretic peptide function.

Technologies We Use

We used a rational drug design approach to discover and develop proprietary peptide, peptide mimetic and small molecule agonist compounds, focusing on melanocortin and natriuretic peptide receptor systems. Computer-aided drug design models of receptors are optimized based on experimental results obtained with peptides and small molecules that we develop. With our approach, we believe we are developing an advanced understanding of the factors which drive agonism.

We have developed a series of proprietary technologies used in our drug development programs. One technology employs novel amino acid mimetics in place of selected amino acids. These mimetics provide the receptor-binding functions of conventional amino acids while providing structural, functional and physiochemical advantages. The amino acid mimetic technology is employed in PL-3994, our compound in development for treatment of heart failure.

Some compound series have been derived using our proprietary and patented platform technology, called MIDAS™, or Metal Ion-induced Distinctive Array of Structures. This technology employs metal ions to fix the three-dimensional configuration of peptides, forming conformationally rigid molecules that remain folded specifically in their active state. These MIDAS molecules are generally simple to synthesize, are chemically and proteolytically stable, and have the potential to be orally bioavailable. In addition, MIDAS molecules are information-rich and provide data on structure-activity relationships that may be used to design small molecule, non-peptide drugs.

Amount Spent on Research and Development Activities

Research and development expenses were approximately $32.6 million for the fiscal year ended June 30, 2018 ("fiscal 2018"), $45.7 million for the fiscal year ended June 30, 2017 ("fiscal 2017"), and $43.1 million for the fiscal year ended June 30, 2016 ("fiscal 2016").

Competition

General. Our products under development will compete on the basis of quality, performance, cost effectiveness and application suitability with numerous established products and technologies. We have many competitors, including pharmaceutical, biopharmaceutical and biotechnology companies. Furthermore, there are several well-established products in our target markets that we will have to compete against. Products using new technologies which may be competitive with our proposed products may also be introduced by others. Most of the companies selling or developing competitive products have financial, technological, manufacturing and distribution resources significantly greater than ours and may represent significant competition for us. In addition, if any of our product candidates are approved by FDA, they will eventually face competition from generic versions that will sell at significantly reduced prices, be preferred by managed care and health insurance payers, and be eligible for automatic pharmacy substitution even when a prescriber writes a prescription for our product. The timing and extent of future generic competition is dependent upon both our intellectual property rights and the FDA regulatory process, but cannot be accurately predicted.

The pharmaceutical and biotechnology industries are characterized by extensive research efforts and rapid technological change. Many biopharmaceutical companies have developed or are working to develop products similar to ours or that address the same markets. Such companies may succeed in developing technologies and products that are more effective or less costly than any of those that we may develop. Such companies may be more successful than us in developing, manufacturing and marketing products.

We cannot guarantee that we will be able to compete successfully in the future or that developments by others will not render our proposed products under development or any future product candidates obsolete or noncompetitive or that our collaborators or customers will not choose to use competing technologies or products.

Vyleesi for Treatment of HSDD. There is competition and financial incentive to develop, market and sell drugs for the treatment of HSDD and other forms of FSD. Flibanserin, sold under the trade name Addyi®, is the only drug currently approved in the United States for treatment of HSDD. Flibanserin, a non-hormonal oral serotonin 5-HT1A agonist, 5-HT2A antagonist, which requires chronic dosing, was approved by the FDA on August 18, 2015 for treatment of premenopausal women with HSDD. The FDA approval included a risk evaluation and mitigation strategy ("REMS") because of the increased risk of severe hypotension and syncope due to the interaction between flibanserin and alcohol, and a Boxed Warning to highlight the risks of severe hypotension and syncope in patients who drink alcohol during treatment with flibanserin, in those who also use moderate or strong CYP3A4 inhibitors, and in those who have liver impairment. We are aware of several other drugs at various stages of development, most of which are taken on a chronic, typically once-daily, basis. There are other companies reported to be developing new drugs for FSD indications, some of which may be in clinical trials in the United States or elsewhere. We are not aware of any other company actively developing a melanocortin receptor agonist drug for HSDD.

PL-3994 and PL-5028 for Heart Failure Indications. Nesiritide (sold under the trade name Natrecor®), a recombinant human B-type natriuretic peptide drug, is marketed in the United States by Scios Inc., a Johnson & Johnson company. Nesiritide is approved for treatment of acutely decompensated congestive heart failure patients who have dyspnea at rest or with minimal activity. Other peptide drugs, including carperitide, a recombinant human ANP drug, and ularitide, a synthetic form of urodilatin, a naturally occurring human natriuretic peptide related to ANP, have been

investigated for treatment of congestive heart failure, but we are not aware of any active development in the United States. We are aware of other companies developing intravenously administered natriuretic peptide drugs, with at least one reported to have completed Phase 2 clinical trials for acute heart failure. A combination drug comprised of sacubitril and valsartan developed by Novartis AG, sold under the trade name Entresto®, inhibits both the angiotensin II receptor and neprilysin (an enzyme which inactivates endogenous active natriuretic peptides). This combination drug, which was approved by the FDA in July 2015, results in increases of endogenous active ANP levels, and thus has a mechanism of action with similarities to PL-3994 and PL-5028. In a Phase 3 trial, the combination drug was compared to an angiotensin-converting-enzyme inhibitor, enalapril, in heart failure patients with reduced ejection fraction. It significantly improved the rate of death from cardiovascular causes, significantly reduced hospitalization for heart failure and significantly improved heart failure symptoms. This combination drug demonstrated that upregulation of the natriuretic peptide system in combination with angiotensin-converting-enzyme inhibition is superior to angiotensin-converting-enzyme inhibition alone, and thus provides validation of the natriuretic peptide system as a target for improving outcomes in treating heart failure patients. In addition, there are a number of approved drugs and drugs in development for treatment of heart failure through mechanisms or pathways other than agonism of NPR-A.

MC1r Peptides for Inflammatory Disease-Related Indications. Many inflammatory disease-related indications are treated using systemic steroids or immunosuppressant drugs, all of which have side effects which can be dose limiting. There are a large number of approved biological drugs and biological drugs under development for treatment of inflammatory disease-related indications. For inflammatory bowel diseases, FDA-approved drugs include mesalazine and immunosuppressive drugs such as prednisone and other steroids, tumor necrosis factor inhibitors such as infliximab and adalimumab, and immune system suppressants such as azathioprine, mercaptopurine and methotrexate.

Mild to moderate dry eye disease and other ocular inflammatory diseases may be treated with artificial tear eye drops, lubricating tear ointments, hot compresses or punctual plugs, but more severe disease may be treated with topical immunosuppressants such as cyclosporine ophthalmic emulsions, including Restasis® marketed in the United States by Allergan, Inc., or with drugs inhibiting inflammatory cell binding, such as lifitegrast, including Xiidra® marketed in the United States by Shire US Inc. In addition, there are a number of drugs in clinical development for treatment of dry eye disease, with 19 agents reported to be in or have completed Phase 2 development. There are no reported MC1r agonist drugs in clinical trials for dry eye disease. If one or more of these competing product candidates is approved and either treats the signs and symptoms of dry eye disease or reduces the frequency of flares of dry eye in patients, it could reduce the market for our MC1r drugs.

Obesity and Related Indications. There are a number of FDA-approved drugs and medical devices for the treatment of obesity, and a large number of products in clinical development by other companies, including products which target melanocortin receptors. Rhythm Pharmaceuticals, Inc. is reported to be in Phase 3 clinical trials with an MC4r agonist peptide drug for rare genetic disorders of obesity.

Patents and Proprietary Information

Patent Protection. Our success will depend in substantial part on our ability to obtain, defend and enforce patents, maintain trade secrets and operate without infringing upon the proprietary rights of others, both in the United States and abroad. We own a number of issued United States patents and have pending United States patent applications, many with issued or pending counterpart patents in selected foreign countries. We seek patent protection for our technologies and products in the United States and those foreign countries where we believe patent protection is commercially important.

We own two issued United States patents claiming the Vyleesi substance and an issued patent claiming the Vyleesi substance in each of Australia, Austria, Belgium, Brazil, Canada, Cyprus, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, Monaco, Netherlands, New Zealand, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. The issued United States patents have a term until 2020, and the term of one patent covering either the composition of matter or method of use of Vyleesi may be subject to extension for a maximum period of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process, pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. Whether we will be able to obtain a patent term extension under the Hatch-Waxman Amendments and the length of any such extension cannot be determined until the FDA approves for marketing, if ever, a product in which Vyleesi is the active ingredient. In addition, the claims of issued patents covering Vyleesi may not provide meaningful protection. Further, third parties may challenge the validity or scope of any issued patent, and under the Hatch-Waxman Amendments, potentially receive approval of a competing generic version of our product or products even before a court rules on the validity or infringement of our patents.

We own two issued United States patents and a pending patent application in the United States for methods of treating FSD with Vyleesi, with related patents issued in Australia and South Africa, and related patent applications pending in Brazil, Canada, China, Georgia, Hong Kong, India, Indonesia, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, Philippines, Ukraine, Vietnam and before the European and Eurasian patent offices. Under our license agreement with

AMAG, AMAG has assumed responsibility for prosecution in the United States, Canada and Mexico. The issued United States patents have a term until 2033. We do not know the full scope of patent coverage we will obtain, or whether any patents will issue other than the patents already issued. Whether we will be able to obtain a patent term extension in the United States under the Hatch-Waxman Amendments, and the length of any such extension, cannot be determined until the FDA approves for marketing, if ever, a product utilizing Vyleesi by methods claimed in the patent. Issued patents and pending applications in the United States and elsewhere in the world have a presumptive term, if a patent is issued, until 2033.

We have patents and patent applications on an alternative class of melanocortin receptor-specific peptides for treatment of sexual dysfunction and other indications, including obesity, consisting of two issued patents in the United States, an issued patent in each of Australia, Canada, China, France, Germany, Ireland, Israel, Japan, Korea, Mexico, New Zealand, Russia, Switzerland and the United Kingdom, and pending patent applications on the same class in Brazil, and South Africa. The presumptive term of the issued patents and pending patent applications is until 2029. We also have patents and pending patent applications for a second class of alternative melanocortin receptor-specific peptides for treatment of sexual dysfunction and other indications, including obesity, consisting of issued patents in the United States, Australia, China, France, Germany, Ireland, Japan, Israel, Korea, New Zealand, Russia, South Africa, Switzerland and the United Kingdom and pending patent applications on the same class in Brazil, Canada, China, India, and Mexico. The presumptive term of the issued patents and pending patent applications is until 2030. Until one or more product candidates covered by a claim of one of these patents and patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We own four issued patents in the United States, and issued patents in Canada, China, Israel, Japan, Mexico, New Zealand, South Africa and Russia claiming highly selective MC1r agonist peptides, including for treatment of inflammation-related diseases and disorders and related indications, and pending patent applications in Australia, Brazil, India, and Korea. The presumptive term of the issued patents and pending patent applications is until 2030. Until one or more product candidates covered by a claim of one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We own two issued United States patents claiming the PL-3994 substance and other natriuretic peptide receptor agonist compounds that we have developed and an issued United States patent claiming a precursor molecule to the PL-3994 substance, both of which expire in 2027. Corresponding patents on the PL-3994 substance and other natriuretic peptide receptor agonist compounds were issued in Australia, Austria, Belgium, China, Colombia, Denmark, Finland, France, Germany, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Korea, Mexico, Netherlands, Philippines, Russia, South Africa, Spain, Sweden, Switzerland, and the United Kingdom, with terms until 2027. Patent applications on the PL-3994 substance and other natriuretic peptide receptor agonist compounds are pending in Brazil and Canada, with presumptive terms until 2027. Applications claiming precursor molecules for the PL-3994 substance and other compounds have issued in the United States, Australia, Canada, China, France, Germany, Hong Kong, India, Ireland, Israel, Japan, Mexico, Netherlands, Philippines, Korea, South Africa, Sweden, Switzerland and the United Kingdom, and expire in 2027. A Patent application on the precursor molecule is pending in Brazil, with presumptive terms until 2027. We also own an issued United States patent claiming use of the PL-3994 substance for treatment of acute asthma and chronic obstructive pulmonary disease, which expires in 2031. Until one or more product candidates covered by a claim of the issued patents or one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We additionally have 35 issued United States patents on melanocortin receptor specific peptides and small molecules, and five issued United States patents on natriuretic peptide receptor agonist compounds, but we are not actively developing any product candidate covered by a claim of any of these patents.

In the event that a third party has also filed a patent application relating to an invention we claimed in a patent application, we may be required to participate in an interference proceeding adjudicated by the United States Patent and Trademark Office (“USPTO”) to determine priority of invention. The possibility of an interference proceeding could result in substantial uncertainties and cost, even if the eventual outcome is favorable to us. An adverse outcome could result in the loss of patent protection for the subject of the interference, subjecting us to significant liabilities to third parties, the need to obtain licenses from third parties at undetermined cost, or requiring us to cease using the

technology. Additionally, the claims of our issued patents may be narrowed or invalidated by administrative proceedings, such as interference or derivation, inter partes review, post grant review or reexamination proceedings before the USPTO.

Future Patent Infringement. We do not know for certain that our commercial activities will not infringe upon patents or patent applications of third parties, some of which may not even have been issued. Although we are not aware of any valid United States patents which are infringed by Vyleesi or PL-3994, we cannot exclude the possibility that such patents might exist or arise in the future. We may be unable to avoid infringement of any such patents and may have to seek a license, defend an infringement action, or challenge the validity of such patents in court. Patent litigation is costly and time consuming. If such patents are valid and we do not obtain a license under any such patents, or we are found liable for infringement, we may be liable for significant monetary damages, may encounter significant delays in bringing products to market, or may be precluded from participating in the manufacture, use or sale of products or methods of treatment covered by such patents.

Proprietary Information. We rely on proprietary information, such as trade secrets and know-how, which is not patented. We have taken steps to protect our unpatented trade secrets and know-how, in part through the use of confidentiality and intellectual property agreements with our employees, consultants and certain contractors. If our employees, scientific consultants, collaborators or licensees develop inventions or processes independently that may be applicable to our product candidates, disputes may arise about the ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights.

If trade secrets are breached, our recourse will be solely against the person who caused the secrecy breach. This might not be an adequate remedy to us because third parties other than the person who causes the breach will be free to use the information without accountability to us. This is an inherent limitation of the law of trade secret protection.

U.S. Governmental Regulation of Pharmaceutical Products

General

Regulation by governmental authorities in the United States and other countries will continue to significantly impact our research, product development, manufacturing and marketing of any pharmaceutical products. The nature and the extent to which regulations apply to us will vary depending on the nature of any such products. Our potential pharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. The products we are developing are subject to federal regulation in the United States, principally by the FDA under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and by state and local governments, as well as regulatory and other authorities in foreign governments that include rigorous preclinical and clinical testing and other approval procedures. Such regulations govern or influence, among other things, the research, development, testing, manufacture, safety and efficacy requirements, labeling, storage, recordkeeping, licensing, advertising, promotion, distribution and export of products, manufacturing and the manufacturing process. In many foreign countries, such regulations also govern the prices charged for products under their respective national social security systems and availability to consumers.

All drugs intended for human use are subject to rigorous regulation by the FDA in the United States and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before an innovative new drug product may be marketed in the United States are similar to steps required in most other countries and include, but are not limited to:

completion of preclinical laboratory tests, preclinical animal testing and formulation studies;

submission to the FDA of an IND, which must be in effect before clinical trials may commence;

submission to the FDA of an NDA that includes preclinical data, clinical trial data and manufacturing information;

payment of substantial user fees for filing the NDA and other recurring user fees;

FDA review of the NDA;

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and

FDA approval of the NDA, including approval of all product labeling.

For combination products deemed to have a "drug" primary mode of action, primary review of the product will be conducted by the appropriate division within the Center for Drug Evaluation and Research ("CDER"), but CDER will consult with the Center for Devices and Radiological Health to ensure that the device components of the product meet

all applicable device requirements.

The research, development and approval process requires substantial time, effort and financial resources, and approvals may not be granted on a timely or commercially viable basis, if at all.

Preclinical testing includes laboratory evaluations to characterize the product's composition, impurities, stability, and mechanism of its pharmacologic effect, as well as animal studies to assess the potential safety and efficacy of each product. Preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices and the U.S. Department of Agriculture's Animal Welfare Act. Violations of these laws and regulations can, in some cases, lead to invalidation of the tests, requiring such tests to be repeated and delaying approval of the NDA. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Unless the FDA objects to an IND by placing the study on clinical hold, the IND will go into effect 30 days following its receipt by the FDA. The FDA may authorize trials only on specified terms and may suspend ongoing clinical trials at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks. If the FDA places a study on clinical hold, the sponsor must resolve all of the FDA's concerns before the study may begin or continue. The IND application process may become extremely costly and substantially delay development of products. Similar restrictive requirements also apply in other countries. Additionally, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials involve the administration of the investigational product to humans under the supervision of qualified principal investigators. Our clinical trials must be conducted in accordance with Good Clinical Practice regulations under protocols submitted to the FDA as part of an IND. In addition, each clinical trial is approved and conducted under the auspices of an institutional review board ("IRB"), and requires the patients' informed consent. An IRB considers, among other things, ethical factors, the safety of human subjects, and the possibility of liability of the institutions conducting the trial. The IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for a variety of reasons, including a belief that the test subjects are being exposed to an unacceptable health risk. As the sponsor, we can also suspend or terminate a clinical trial at any time.

Clinical trials are typically conducted in three sequential phases, Phases 1, 2, and 3, involving an increasing number of human subjects. These phases may sometimes overlap or be combined. Phase 1 trials are performed in a small number of healthy human subjects or subjects with the targeted condition, and involve testing for safety, dosage tolerance, absorption, distribution, metabolism and excretion. Phase 2 studies, which may involve up to hundreds of subjects, seek to identify possible adverse effects and safety risks, preliminary information related to the efficacy of the product for specific targeted diseases, dosage tolerance, and optimal dosage. Finally, Phase 3 trials may involve up to thousands of individuals often at geographically dispersed clinical trial sites, and are intended to provide the documentation of effectiveness and important additional safety data required for approval. Prior to commencing Phase 3 clinical trials many sponsors elect to meet with FDA officials to discuss the conduct and design of the proposed trial or trials.

In addition, federal law requires the listing, on a publicly-available website, of detailed information on clinical trials for investigational drugs. Some states have similar or supplemental clinical trial reporting laws.

Success in early-stage animal studies and clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from animal studies and clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval.

All data obtained from the preclinical studies and clinical trials, in addition to detailed information on the manufacture and composition of the product, would be submitted in an NDA to the FDA for review and approval for the manufacture, marketing and commercial shipments of any of our products. FDA approval of the NDA is required before commercial marketing or non-investigational interstate shipment may begin in the United States. The FDA may also conduct an audit of the clinical trial data used to support the NDA.

The FDA may deny or delay approval of an NDA that does not meet applicable regulatory criteria. For example the FDA may determine that the preclinical or clinical data or the manufacturing information does not adequately establish the safety and efficacy of the drug. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA. The FDA can request additional information, seek clarification regarding information already provided in the submission or ask that new additional clinical trials be conducted, all of which can delay approval. Similar types of regulatory processes will be encountered as efforts are made to market any drug internationally. We will be required to assure product performance and manufacturing processes from one country to another.

Even if the FDA approves a product, it may limit the approved uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval or limit labeling. Once it approves an NDA, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products, and

may limit further marketing of the product based on the results of these post-market studies. The FDA and other government agencies have broad post-market regulatory and enforcement powers, including the ability to levy civil and criminal penalties, suspend or delay issuance of approvals, seize or recall products and revoke approvals.

Pharmaceutical manufacturers, distributors and their subcontractors are required to register their facilities with the FDA and state agencies. Manufacturers are required to list their marketed drugs with the FDA, are subject to periodic inspection by the FDA and other authorities, where applicable, and must comply with the FDA's current Good Manufacturing Practices ("GMP") regulations, and the product specifications set forth in the approved NDA. The GMP requirements for pharmaceutical products are extensive and compliance with them requires considerable time, resources and ongoing investment. The regulations require manufacturers and suppliers of raw materials and components to establish validated systems and to employ and train qualified employees to ensure that products meet high standards of safety, efficacy, stability, sterility (where applicable), purity, and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the drug product. For all drug products, the regulations require investigation and correction of any deviations from GMP requirements and impose documentation requirements upon us and any third-party manufacturers that we may decide to use. Manufacturing establishments are subject to mandatory user fees, and to periodic unannounced inspections by the FDA and state agencies for compliance with all GMP requirements. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner.

We or our present or future suppliers may not be able to comply with GMP and other FDA regulatory requirements. Failure to comply with the statutory and regulatory requirements subjects the manufacturer and/or the NDA sponsor or distributor to possible legal or regulatory action, such as a delay or refusal to approve an NDA, suspension of manufacturing, seizure or recall of a product, or civil or criminal prosecution of the company or individual officers or employees.

Post-Marketing Regulation

Any drug products manufactured or distributed by us pursuant to FDA approvals, as well as the materials and components used in our products, are subject to pervasive and continuing regulation by the FDA, including:

recordkeeping requirements;

periodic reporting requirements;

GMP requirements related to all stages of manufacturing, testing, storage, packaging, labeling and distribution of finished dosage forms of the product;

monitoring and reporting of adverse experiences with the product; and

advertising and promotional reporting requirements and restrictions.

Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or product removal. Product approvals may be revoked if compliance with regulatory requirements is not maintained or if problems concerning safety or effectiveness of the product occur following approval. The FDA is developing a national electronic drug safety tracking system known as SENTINEL that may impose additional safety monitoring burdens, and enhanced FDA enforcement authority, beyond the extensive requirements already in effect. As a condition of NDA approval, the FDA may require post-approval testing and surveillance to monitor a product's safety or efficacy. The FDA also may impose other conditions, including labeling restrictions which can materially impact the potential market and profitability of a product.

With respect to post-market product advertising and promotion, the FDA and other government agencies including the Department of Health and Human Services and the Department of Justice, and individual States, impose a number of complex regulations on entities that advertise and promote pharmaceuticals, including, among others, standards and restrictions on direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in administrative and judicial enforcement actions, including the issuance of a Warning Letter directing correction of deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, False Claims Act prosecution based on alleged off-label marketing seeking monetary and other penalties, including potential exclusion of the drug and/or the company from participation in government health care programs, and state and federal civil and criminal investigations and prosecutions. Foreign regulatory bodies also strictly enforce these and other regulatory requirements and drug marketing may be prohibited in whole or in part in other countries.

We, our collaborators or our third-party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in:

restrictions on the marketing or manufacturing of a product;

Warning Letters or Untitled Letters from the FDA asking us, our collaborators or third-party contractors to take or refrain from taking certain actions;

withdrawal of the product from the market;

the FDA’s refusal to approve pending applications or supplements to approved applications;

voluntary or mandatory product recall;

fines or disgorgement of profits or revenue;

suspension or withdrawal of regulatory approvals;

refusals to permit the import or export of products;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

We may also be subject to healthcare laws, regulations and enforcement and our failure to comply with any such laws, regulations or enforcement could adversely affect our business, operations and financial condition. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal physician sunshine requirements under the Patient Protection and Affordable Care Act ("Affordable Care Act"), which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; 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; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be

provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Generic Competition

Orange Book Listing. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, the applicant identifies all patents that claim the approved product's active ingredient(s), the drug product's approved formulation, or an approved method of use of the drug. Each of the identified patents are then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing, unless such testing is waived by the FDA, as is the case with some injectable drug products, to be therapeutically equivalent to the listed drug. Other than bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can usually be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify either that: (1) the required patent information has not been filed (a Paragraph I Certification); (2) the listed patent has expired (a Paragraph II Certification); (3) the listed patent has not expired, but will expire on a particular date and the generic approval is being sought only after patent expiration (a Paragraph III Certification); or (4) the listed patent is invalid, unenforceable, or will not be infringed by the proposed generic product (a Paragraph IV Certification). In certain circumstances, the ANDA applicant may also elect to submit a "section (viii)" statement instead of a Paragraph IV Certification, certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the application contains only Paragraph I or Paragraph II Certifications, the ANDA may be approved as soon as FDA completes its review and concludes that all approval requirements have been met. If the ANDA contains one or more Paragraph III Certifications, the ANDA cannot not be approved until each listed patent for which a Paragraph III Certification was filed have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA holder and patent owner once the ANDA has been accepted for filing by the FDA. The patent owner or NDA holder may then commence a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months (the "30-month stay"), expiration of the patent, settlement of the lawsuit in which the patent owner admits that the patent is invalid or not infringed by the ANDA product, or a decision in the infringement case that holds the patent to be invalid or not infringed, or an order by the court shortening the 30-month stay due to actions by the patent holder to delay the litigation. In most circumstances, NDA holder is only eligible for one 30-month stay against an ANDA.

If a patent infringement action is filed against an ANDA applicant, any settlement of the litigation must be submitted to the Federal Trade Commission ("FTC"). If the FTC believes the terms or effects of the settlement are anticompetitive,

FTC may bring an antitrust enforcement action against the parties. Private parties may also bring antitrust lawsuits against drug companies based on such patent litigation settlements.

The ANDA also will not be approved until any applicable non-patent regulatory exclusivity listed in the Orange Book for the referenced product has expired.

Regulatory Exclusivity. Upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive for review any ANDA seeking approval of a generic version of that drug. An ANDA containing a Paragraph IV Certification may be received by FDA 4 years after the NCE drug's approval, but any 30-month stay that ensues would be extended so that it expires seven and one half years after the NCE approval date, subject to early termination by reason of a court decision or settlement as described above.

Certain changes to an NDA drug, such as the addition of a new indication to the package insert, for which new clinical trials, conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the change, can be eligible for a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change. An ANDA that contains a section (viii) statement to a method of use patent may be approved with labeling that omits the patented use before the use patent expires. Generic drugs approved with such a labeling carve out may be substituted by pharmacists for the original branded drug before the method of use patent expires.

Section 505(b)(2) NDAs. Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. A 505(b)(2) NDA may be used where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication or conditions of use sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the expiration of any 30-month stay, subject to early termination of the stay as described above.

Changing Legal and Regulatory Landscape

Periodically, legislation is introduced in the U.S. Congress that could change the statutory and regulatory provisions governing the approval, manufacturing and marketing of our drugs. In addition, the FDCA, FDA regulations and guidance are often revised or reinterpreted by the FDA or the courts in ways that may significantly affect our business and products. We cannot predict whether or when legislation or court decisions impacting our business will be enacted or issued, what FDA regulations, guidance or interpretations may change, or what the impact of such changes, if any, may be in the future.

Third-Party Reimbursements

Successful sales of our proposed products in the United States and other countries depend, in large part, on the availability of adequate reimbursement from third-party payers such as governmental entities, managed care organizations, health maintenance organizations ("HMOs"), and private insurance plans. Reimbursement by a third-party payer depends on a number of factors, including the payer's determination that the product has been approved by the FDA for the indication for which the claim is being made, that it is neither experimental nor investigational, and that the use of the product is safe and efficacious, medically necessary, appropriate for the specific patient and cost effective.

Since reimbursement by one payer does not guarantee reimbursement by another, we or our licensees may be required to seek approval from each payer individually. Seeking such approvals is a time-consuming and costly process. Third-party payers routinely limit the products that they will cover and the amount of money that they will pay and, in many instances, are exerting significant pressure on medical suppliers to lower their prices.

Payers frequently employ a tiered system in reimbursing end users for pharmaceutical products, with tier designation affecting copay or deductible amounts. The only approved product for treating HSDD is flibanserin, sold under the trade name Addyi®. There is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating HSDD. Based on third-party reimbursement for approved products treating ED, we believe Vyleesi will be classified as a Tier 3 drug, so that reimbursement will be limited for Vyleesi for treatment of premenopausal women with HSDD, assuming the product is approved by the FDA. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of Vyleesi. Further, healthcare reimbursement systems vary from country to country, and third-party reimbursement might not be made available for Vyleesi for HSDD under any other reimbursement system.

Manufacturing and Marketing

To be successful, our proposed products will need to be manufactured in commercial quantities under GMP prescribed by the FDA and at acceptable costs. We do not have the facilities to manufacture any of our proposed products under GMP. We intend to rely on collaborators, licensees or contract manufacturers for the commercial manufacture of our proposed products.

Our Vyleesi product candidate is a synthetic peptide. While the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under GMP at acceptable costs. We identified one third-party manufacturer for the production of Vyleesi, Lonza Ltd., and have validated manufacturing of the Vyleesi drug substance under GMP with that manufacturer. AMAG, as the exclusive licensee for North America, has assumed responsibility for manufacturing Vyleesi drug substance.

Our Vyleesi product candidate will be a combination product, incorporating both the Vyleesi drug substance and a delivery device. AMAG, as the exclusive licensee for North America, has assumed responsibility for manufacturing the Vyleesi combination product. A third-party manufacturer, Ypsomed AG, makes the selected autoinjector pen delivery device. A third-party contract manufacturer, Catalent Belgium S.A., performs fill and finish of the Vyleesi product candidate. We negotiated a long-term commercial supply agreement with Catalent Belgium S.A., and have assigned this agreement to AMAG.

Our PL-3994 product candidate is a peptide mimetic molecule, incorporating a proprietary amino acid mimetic structure and amino acids. We identified a manufacturer that made the product in quantities sufficient for Phase 1 and Phase 2, and are evaluating commercial-scale manufacturers. Scaling up to commercial quantities may involve production, purification, formulation and other problems not present in the scale of manufacturing done to date.

Our MC1r and MC4r agonist product candidates are synthetic peptides, which other than PL-8177, we have manufactured only at laboratory scale. Other than PL-8177, we have not contracted with a third-party manufacturer to produce these synthetic peptides for either clinical trials or commercial purposes. While the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under GMP at acceptable costs. Additionally, scaling up to commercial quantities may involve production, purification, formulation and other problems not present in the scale of manufacturing done to date.

The failure of any manufacturer or supplier to comply with FDA regulations, including GMP or medical device quality systems regulations (“QSR”), or to supply the device component or drug substance and services as agreed, would force us or our licensees to seek alternative sources of supply and could interfere with our and our licensees’ ability to deliver product on a timely and cost-effective basis or at all. Establishing relationships with new manufacturers or suppliers, any of whom must be FDA-approved, is a time-consuming and costly process.

Product Liability and Insurance

Our business may be affected by potential product liability risks that are inherent in the testing, manufacturing, marketing and use of our proposed products. We have liability insurance providing $10 million coverage in the aggregate as to certain clinical trial risks.

Employees

As of September 11, 2018, we employed 19 people full time, of whom 13 are engaged in research and development activities and 6 are engaged in administration and management, and did not have any part-time employees. While we have been successful in attracting skilled and experienced scientific personnel, competition for personnel in our

industry is intense. None of our employees are covered by a collective bargaining agreement. All of our employees have executed confidentiality and intellectual property agreements. We consider relations with our employees to be good.

We rely on contractors and scientific consultants to work on specific research and development programs. We also rely on independent organizations, advisors and consultants to provide services, including aspects of manufacturing, testing, preclinical evaluation, clinical management, regulatory strategy and market research. Our independent advisors, contractors and consultants sign agreements that provide for confidentiality of our proprietary information and that we have the rights to any intellectual property developed while working for us.

Corporate Information

We were incorporated under the laws of the State of Delaware on November 21, 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 www.palatin.com, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, 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) 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 Annual Report. The reference to our website is an inactive textual reference only.

Item 1A. Risk Factors.

Risks Related to Our Financial Results and Need for Financing

We have a history of substantial net losses, and expect to continue to incur substantial net losses over the next few years, and we may never achieve or maintain profitability.

As of June 30, 2018, we had an accumulated deficit of $332.0 million. We had $24.7 million of net income for the year ended June 30, 2018 and we may attain profitability in the fiscal year ending June 30, 2019 but only if the FDA approves the NDA on Vyleesi for HSDD. Even if we are profitable in fiscal 2019, we may not sustain profitability in future years, depending on numerous factors, including whether and when development and sales milestones are met, regulatory actions by the FDA and other regulatory bodies, the performance of our licensees, and market acceptance of our products.

We expect to incur significant expenses as we continue our development of natriuretic peptide and MC1r products. These expenses, 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 not received any 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 license and 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 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 will need additional funding, including funding to complete clinical trials for our product candidates other than Vyleesi, which may not be available on acceptable terms, if at all.

We intend to focus future efforts on our product candidates other than Vyleesi, including our MC1r and natriuretic peptide programs. As of June 30, 2018, we had cash and cash equivalents of $38.0 million, with current liabilities of $10.8 million. We believe we currently have sufficient existing capital resources, together with proceeds received from sales of common stock in our "at-the-market" program (if any), to fund our planned operations through at least September 30, 2019. We will need additional funding to complete development activities and required clinical trials for our other product candidates and development programs and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA.

Until the FDA approves Vyleesi for HSDD and marketing commences, if at all, we will not have any recurring revenue. Even if Vyleesi is approved and marketing commences, we cannot predict product sales or our resulting royalties, so we may not have any source of significant recurring revenue and may need to 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, such financing arrangements 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:

our ability to enter into one or more licensing or similar agreements for Vyleesi outside of North America, Korea and China;

the timing of, and the costs involved in, obtaining regulatory approvals for Vyleesi for HSDD 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 our future product candidates, and conducting preclinical and clinical trials;

the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing any future product candidates and any products we successfully commercialize;

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.

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, through contract manufacturers, our principal product candidates on a small-scale basis. These operations provide a limited basis for stockholders to assess our ability to commercialize our product candidates.

While we have completed Phase 3 clinical trials on Vyleesi for HSDD in premenopausal women, and with AMAG have filed an NDA on Vyleesi for HSDD with the FDA, 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;

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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 the FDA's current Good Manufacturing Practices ("GMP") regulations;

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 develop, 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.

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, Vyleesi for HSDD, but we and our licensees may never obtain regulatory approval for or successfully commercialize Vyleesi for HSDD or any of our product candidates.

To date, we have invested most of our efforts and financial resources in the research and development of Vyleesi for HSDD, which is currently our lead product candidate. We licensed all rights to Vyleesi in North America to AMAG, and were contractually obligated to complete development and regulatory activities necessary to file an NDA for Vyleesi for HSDD in the United States, for which AMAG reimbursed us for $25 million of expenses we incurred less certain other expenses directly paid or to be paid by AMAG. We licensed rights to Vyleesi for China to Fosun and licensed rights to Vyleesi for Korea to Kwangdong, but depending on the regulatory approval pathway utilized in China or Korea, approval in China or Korea may be contingent on approval of an NDA for Vyleesi for HSDD in the United States.

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 Vyleesi for HSDD, 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 and studies, for our product candidates, 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;

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

whether we or our licensees are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of Vyleesi for HSDD 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 Vyleesi for HSDD;

the success of our licensees in educating physicians and patients about the benefits, administration and use of Vyleesi for HSDD, if approved;

the prevalence and severity of adverse events experienced with Vyleesi for HSDD 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 the Vyleesi 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 Vyleesi for HSDD 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;

the ability to manufacture clinical trial supplies of Vyleesi for HSDD or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current GMP;

the ability of AMAG to successfully commercialize Vyleesi for HSDD;

our ability to successfully commercialize 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 Vyleesi for HSDD or any future product candidates;

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

acceptance of Vyleesi for HSDD 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 Vyleesi for HSDD or any future product candidates following approval.

If we fail to satisfy any one of these prerequisites to our commercial success, 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 Vyleesi for HSDD by AMAG, Fosun and Kwangdong or through the sale of any future product candidate to continue our business. In addition to preventing us from executing our current business plan, any delays in our clinical trials, or inability to successfully commercialize our products could impair our reputation in the industry and the investment community and could hinder our ability to fulfill our existing contractual commitments. As a result, our share price would likely decline significantly, and we would have difficulty raising necessary capital for future projects.

We do not control the development or commercialization of Vyleesi in North America, which is licensed to AMAG, and as a result we may not realize a significant portion of the potential value of the license arrangement with AMAG.

Although we conducted development work to support an NDA for Vyleesi in HSDD, the license agreement with AMAG for Vyleesi in North America limits our control over development activities, including regulatory approvals, and we do not have any direct control over commercialization efforts. AMAG may abandon further development of Vyleesi in its licensed territory, including terminating the agreement, for any reason, including a change of priorities within AMAG or lack of success in ancillary clinical trials necessary to obtain regulatory approvals. Because the potential value of the license arrangement with AMAG is contingent upon the successful development and commercialization of Vyleesi in the United States and other countries in the licensed territory, the ultimate value of this license will depend on the efforts of AMAG. If AMAG does not succeed in obtaining regulatory approval of Vyleesi in the United States for any reason, does not succeed in securing market acceptance of Vyleesi in the United States, or elects for any reason to discontinue marketing of Vyleesi, we will be unable to realize the potential value of this arrangement and would experience significant delays or an inability to successfully commercialize Vyleesi.

Production and supply of Vyleesi depend on contract manufacturers over whom neither we nor AMAG have any control, and we may not have adequate supplies of Vyleesi.

We do not have the facilities to manufacture the Vyleesi active drug ingredient or the autoinjector pen component of the Vyleesi combination product, or to fill, assemble and package the Vyleesi combination product. AMAG, our exclusive licensee for North America for Vyleesi, has assumed responsibility for contract manufacturing. The contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. AMAG's ability to control third-party compliance with FDA requirements is limited to contractual remedies and rights of inspection. The manufacturers of approved products and their manufacturing facilities will be subject to ongoing review and periodic inspections by the FDA and other authorities where applicable, and must comply with regulatory requirements, including FDA regulations concerning GMP. Failure of third-party manufacturers to comply with GMP, medical device quality system regulations, or other FDA requirements may result in enforcement action by the FDA. Failure to conduct their activities in compliance with FDA regulations could delay Vyleesi development programs or negatively impact AMAG's ability to receive FDA approval of the Vyleesi potential products or continue marketing Vyleesi products if they are approved. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process. If AMAG is not able to obtain adequate supplies of Vyleesi, it will be difficult for AMAG to develop Vyleesi and compete effectively.

Our product candidates other than Vyleesi 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 ("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 ("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 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.

We may not be able to secure and maintain relationships with research institutions and other organizations to conduct our clinical trials.

We rely on research institutions and other organizations to conduct our clinical trials, and we therefore have limited control over the timing and cost of clinical trials and our ability to recruit subjects. If we are unable to reach agreements with suitable research institutions or organizations on acceptable terms, or if any such agreement is terminated, we may be unable to quickly replace the research institution or organization with another qualified institution or organization on acceptable terms. We may not be able to secure and maintain suitable research institutions or organizations to conduct our clinical trials.

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 the safety and effectiveness of any such product;

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 ("HMOs") and government programs such as Medicare and Medicaid; and

advantages over alternative treatment methods.

There is one FDA approved product for treatment of HSDD, flibanserin, which is sold under the trade name Addyi®, and started marketing in October 2015. Because flibanserin was not consistently marketed since October 2015, and ownership of the product has changed, the actual market size and market dynamics for HSDD are unknown, and there remains uncertainty concerning the extent and scope of third-party reimbursement for products treating HSDD. While we believe that an on-demand drug for HSDD 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. Vyleesi is administered by subcutaneous injection. While the single-use, disposable autoinjector pen format is designed to maximize market acceptability, Vyleesi as a subcutaneous injectable drug for HSDD may never achieve significant market acceptance. In addition, we believe reimbursement of Vyleesi from third-party payers such as health insurers, HMOs or other third-party payers of healthcare costs will be similar to reimbursement for erectile dysfunction ("ED") drugs, and that the ultimate user may pay a substantial part of the cost of Vyleesi for HSDD. If the market opportunity for Vyleesi 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 Vyleesi. If Vyleesi for HSDD 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 (either while they 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, which could cause unanticipated delays or higher than anticipated costs.

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. Due to the need to find new subjects for any additional clinical trials and the limited pool from which such subjects can be selected, any such determination by the FDA could result in a delay in obtaining FDA approval or require additional financial expenditures.

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.

Flibanserin, a daily-use oral drug sold under the trade name Addyi®, has been approved by the FDA for HSDD in premenopausal women. There are other products being developed for HSDD and other FSD indications, including a number of oral combination drugs, some of which incorporate testosterone, antidepressants or PDE-5 inhibitors. There is competition to develop drugs for treatment of HSDD and FSD in both premenopausal and postmenopausal patients. Our Vyleesi 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 Vyleesi noncompetitive.

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 indications, and other products are being developed, including products in clinical trials. The dry eye disease and ocular inflammatory disease markets are highly competitive, with a number of products reported in late stage clinical trials.

We are aware of one recombinant NPR product for acutely decompensated congestive heart failure approved and marketed in the United States, and another recombinant NPR 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 ANP.

As discussed above, the biopharmaceutical industry is highly competitive. We are likely to encounter significant competition with respect to Vyleesi, MC1r product candidates, MC4r product candidates and NPR product candidates. 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 Vyleesi or our MC1r product candidates, MC4r product candidates and NPR product candidates. 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 preclinical studies, clinical trials and other research for our product candidates and their failure to timely perform their obligations could significantly harm our product development.

We have limited research and 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 meet expected deadlines or fail to comply with appropriate standards for preclinical or clinical research, 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, with the risk that we may not have adequate supplies of our product candidates or products.

We do not have the facilities to manufacture our early stage potential products such as PL-8177, PL-8331, PL-3994 and other natriuretic peptide and melanocortin receptor agonist compounds for use in preclinical studies and clinical trials. 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 is limited to contractual remedies and rights of inspection. The manufacturers of our potential 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 GMP. Failure of third-party manufacturers to comply with GMP, medical device 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. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

If we are unable to establish sales and marketing capabilities within our organization 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 any experience in sales, marketing and distribution of pharmaceutical products. We will need to establish sales and marketing capabilities within our organization or establish and maintain agreements with third parties to market and sell our product candidates. We do not have marketing partners for any of our products other than Vyleesi, for which we have marketing partners in North America, China and Korea. If any of our other 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. Engaging a third party to perform these services 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 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, 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.

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 is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating HSDD and other forms of FSD. Based on third-party reimbursement for approved products treating ED, we believe Vyleesi for HSDD will be classified as a Tier 3 drug, so that reimbursement will be limited for Vyleesi for treatment of premenopausal women with HSDD, 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 $10 million liability insurance in the aggregate as to certain clinical trial risks, but we do not have and have not obtained quotations for commercial product liability insurance. 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.

Our internal computer systems, or those of our third-party contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

In the ordinary course of our business, we collect, store and transmit confidential information. Despite the implementation of security measures, our internal computer systems and those of our third-party contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on industry accepted measures and technology to secure confidential and proprietary information maintained on our computer systems. However, these measures and technology may not adequately prevent security breaches. While we do not believe that we have experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a loss of clinical trial data for our product candidates that could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology, intellectual property, research and development or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may in the future employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee’s former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we begin commercializing any of our products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

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;

federal civil and criminal false claims laws and civil monetary penalty 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 payors that are false or fraudulent;

HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPPA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;

The federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations

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 Vyleesi, PL-8177, PL-8331, PL-3994 and our other preclinical programs for MC1r and MC4r peptide or small molecule drug candidates and natriuretic 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, including commercialization, who possess significant technical expertise and experience and oversee our development and commercialization 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.

Because we expect Vyleesi for the treatment of HSDD to be classified as a Tier 3 drug with reimbursement by third-party payers similar to approved products for treating ED, demand for this product will be tied to discretionary spending levels of our targeted patient population and particularly affected by unfavorable economic conditions.

The market for HSDD may be particularly vulnerable to unfavorable economic conditions. We expect Vyleesi for the treatment of HSDD to have significant copay or deductible requirements and to be only partially reimbursed by third-party payers and, as a result, demand for this product may 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 Vyleesi for HSDD 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 future economic climates and financial market conditions could adversely impact our business.

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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 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 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 Vyleesi for HSDD even if the product is effective in treating HSDD.

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 Vyleesi for treatment of HSDD in premenopausal women requires a determination by the FDA that the product is both safe and effective. Our Phase 3 clinical trials for HSDD demonstrated what we believe to be an acceptable safety profile and statistically significant efficacy. However, the FDA may ultimately disagree with our safety analysis, definition of efficacy in HSDD, our clinical trial designs, or our interpretation of our clinical trial results. It is not possible to predict, with any assurance, whether the FDA will approve Vyleesi for any indications. The FDA may deny or delay approval of any application for Vyleesi 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 Vyleesi, 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. Vyleesi could take a significantly longer time to obtain approval than we expect and it may never gain approval. If regulatory approval of Vyleesi 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 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 an 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 twelve 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 Vyleesi, 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 (“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 Vyleesi for HSDD 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 Vyleesi for HSDD 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 (“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. Until our products are approved and drug plan formulary listing decisions are made, 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.

The Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (together the "ACA"), was adopted in 2010. This law has resulted in an increase in the number of people who are covered by both public and private insurance and has changed the way health care is financed by both government health program and private insurers, with significant impacts on 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 that we believe will increase the cost of any products that we develop. 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. We cannot predict all of the specific effects the ACA or any future healthcare reform legislation will have on our business, but they could have a material adverse effect on our business and financial condition.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act (the "2017 Tax Act") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the ACA. Because of the continued uncertainty about the implementation of the ACA, including the potential for further legal challenges or repeal of the ACA, we cannot quantify or predict with any certainty the likely impact of the ACA or its repeal on our business, prospects, financial condition or results of operations.

The availability of government reimbursement for prescription drugs will 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 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.

Our patent applications and the enforcement or defense of our issued patents may be impacted by the application of or changes in U.S. and foreign standards.

The standards that the USPTO and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product candidates. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validation enforceability, or term of our patent. For example, the U.S. Supreme Court has recently modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U.S. patent system have come into force under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

While we cannot predict with certainty the impact the Leahy-Smith Act or any potential future changes to the U.S. or foreign patent systems will have on the operation of our business, the Leahy-Smith Act and such future changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

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, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential 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 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 the structure of healthcare payment systems or other actions that affect the effective reimbursement rates for treatment regimens containing our products;

changes in financial estimates and recommendations by securities analysts following our business or our industry;

sales of our common stock (or the perception that such sales could occur); and

the other factors described in this “Risk Factors” section.

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 June 30, 2018, the price of our stock has been volatile, ranging from a high of $1.59 per share to a low of $0.38 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.

As a public company in the United States, we are subject to the Sarbanes-Oxley Act of 2002 (“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 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 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 is 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. 4,030 shares of our Series A Preferred Stock remain outstanding as of September 11, 2018. 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 4,030 shares on September 11, 2018, 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.

We are a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our Common Stock less attractive to investors.

We are currently a “smaller reporting company” as defined in the Exchange Act. Smaller reporting companies are able to provide simplified executive compensation disclosures in their filings, but as an “accelerated filer” we are not exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting, and have certain other decreased disclosure obligations in their SEC filings. We cannot predict whether investors will find our common stock less attractive because of our reliance on the smaller reporting company exemption. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

As of September 11, 2018, there were 45,179,691 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 September 11, 2018, holders of our outstanding dilutive securities had the right to acquire the following amounts of underlying common stock:

61,145 shares issuable on the conversion of our immediately convertible Series A Convertible Preferred Stock, subject to adjustment, for no further consideration;

12,646,312 shares issuable upon the exercise of stock options at a weighted-average exercise price of $0.75 per share;

9,068,188 shares issuable under restricted stock units which vest on dates between December 8, 2018 and June 26, 2022, subject to the fulfillment of service or performance conditions, and some of which are subject to delivery restrictions; and

23,404,046 shares issuable upon the exercise of warrants at a weighted-average exercise price of $0.77 per share.

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 American could result in a de-listing of our common stock.

Our common shares are listed on the NYSE American, a national securities exchange, under the symbol “PTN”. Although we currently meet the NYSE American’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 American’s listing requirements. If we fail to satisfy the continued listing requirements of the NYSE American, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE American may take steps to de-list

our common stock. If the NYSE American 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 American'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 American minimum bid price requirement or prevent future non-compliance with the NYSE American'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 American. 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 American, 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 1B. Unresolved Staff Comments

None.

Item 2.
Properties

Our corporate offices are located at 4B Cedar Brook Drive, Cedar Brook Corporate Center, Cranbury, NJ 08512, where we lease approximately 10,000 square feet of office space under a lease that expires in June 2020. We also lease approximately 1,700 square feet of laboratory space in the Township of South Brunswick, NJ, under a lease that expires in August 2019. We believe our present facilities are adequate for our current needs. We do not own any real property.

Item 3.
Legal Proceedings

We are 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 4.
Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The table below provides, for the fiscal quarters indicated, the reported high and low sales prices for our common stock on the NYSE American (formerly known as the NYSE MKT and NYSE AMEX) since July 1, 2016.

FISCAL YEAR ENDED JUNE 30, 2017	HIGH	LOW
Fourth Quarter	$0.50	$0.29
Third Quarter	0.62	0.32
Second Quarter	0.90	0.45
First Quarter	0.86	0.45

FISCAL YEAR ENDED JUNE 30, 2018	HIGH	LOW
Fourth Quarter	$1.59	$0.87
Third Quarter	1.20	0.83
Second Quarter	1.05	0.65
First Quarter	0.69	0.38

Our common stock has been listed on NYSE American under the symbol "PTN" since December 21, 1999. It previously traded on The Nasdaq SmallCap Market under the symbol "PLTN."

On September 11, 2018, we had approximately 143 record holders of common stock and the closing sales price of our common stock as reported on the NYSE American was $1.05 per share. The aggregate market value of the common and non-voting common equity held by non-affiliates on such date, computed by reference to the closing sales price of our common stock on that date, was $209,647,584.

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 3,295 shares were withheld during the quarter ended June 30, 2018 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	Total Number of Shares Purchased (1)	Weighted Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet be Purchased Under Announced Plans or Programs
April 1-30, 2018	-	$-	-	-
	-	-	-	-

May 1-31, 2018				
June 1-30, 2018	3,295	0.97	-	-
Total	3,295	$0.97	-	-

(1) Consists solely of 3,295 shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock units.

Dividends and dividend policy. We have never declared or paid any dividends. We currently intend to retain earnings, if any, for use in our business. We do not anticipate paying dividends in the foreseeable future.

Dividend restrictions. Our outstanding Series A Preferred Stock, consisting of 4,030 shares on September 11, 2018, 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.

Equity Compensation Plan Information. Reference is made to the information contained in the Equity Compensation Plan table contained in Item 11 of this Annual Report.

Item 6. Selected Financial Data.

Not Applicable.

Item 7.
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 Annual Report.

Forward-Looking Statements

The following discussion and analysis contains forward-looking statements within the meaning of the federal securities laws. You are urged to carefully review our description and examples of forward-looking statements included earlier in this Annual Report on Form 10-K immediately prior to Part I, under the heading "Forward-Looking Statements." Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed in the forward-looking statements. You are urged to carefully review the disclosures we make concerning risks and other factors that may affect our business and operating results, including those made in Part I, Item 1A of this Annual Report on Form 10-K, and any of those made in our other reports filed with the SEC. You are cautioned not to place undue reliance on the forward-looking statements included herein, which speak only as of the date of this document. We do not intend, and undertake no obligation, to publish revised forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 2 to the consolidated financial statements included in this Annual Report. We believe that our accounting policies and estimates relating to revenue recognition, accrued expenses and stock-based compensation charges are the most critical.

Revenue Recognition.

Revenue is recognized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 605-25, Revenue Recognition for Arrangements with Multiple Elements, which addresses the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting. A delivered item within an arrangement is considered a separate unit of accounting only if both of the following criteria are met:

the delivered item has value to the customer on a stand-alone basis; and

if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in control of the vendor.

Under FASB ASC Topic 605-25, if both of the criteria above are not met, then separate accounting for the individual deliverables is not appropriate.

Revenue resulting from the achievement of development milestones is recorded in accordance with the accounting guidance for the milestone method of revenue recognition.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue on the Company's consolidated balance sheet. Amounts expected to be recognized as revenue in the next 12 months

following the balance sheet date are classified as current liabilities.

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. If we do not identify services performed for us but not billed by the service-provider, or if we underestimate or overestimate the value of services performed as of a given date, reported expenses will be understated or overstated.

Stock-based Compensation.

The fair value of stock options granted has been calculated using the Black-Scholes option pricing model, which requires us to make estimates of expected volatility, interest rates and expected option lives. We estimate these factors at the time of grant based on our own prior experience and public sources of information. The amount of recorded compensation related to an option grant is not adjusted for subsequent changes in these estimates or for actual experience. In addition, awards containing a market condition are valued using a multifactor Monte Carlo simulation and awards containing a performance condition require us to estimate the probability of achievement of the performance condition.

The amount and timing of compensation expense to be recorded in future periods related to grants of options and restricted stock units may be affected by the achievement of performance conditions and employment terminations. As a result, stock-based compensation charges may vary significantly from period to period.

See Note 3 to the consolidated financial statements included in this Annual Report for a description of recent accounting pronouncements that affect us.

Results of Operations

Year Ended June 30, 2018 Compared to the Year Ended June 30, 2017:

Revenue – For the fiscal year ended June 30, 2018 (“fiscal 2018”), we recognized $67,134,758 in revenue pursuant to our license agreements with AMAG and Fosun compared to $44,723,827 in revenue for the year ended June 30,2017 (“fiscal 2017”).

On January 8, 2017, we entered into a License Agreement (the “AMAG License Agreement”) with AMAG which provided for $60,000,000 as a one-time initial payment. Pursuant to the terms of and subject to the conditions in the AMAG License Agreement, AMAG reimbursed us $25,000,000, less certain expenses directly paid or to be paid by AMAG for reasonable, documented, direct out-of-pocket expenses we incurred following the effective date of the License Agreement in connection with development and regulatory activities necessary to file an NDA for Vyleesi for HSDD in the United States, less certain other expenses directly paid or to be paid by AMAG. The Company recognized $42,134,758 and $44,723,827 for fiscal 2018 and fiscal 2017 respectively as license and contract revenue which included additional billings for AMAG related Vyleesi costs of $1,151,243 and $707,342 in fiscal 2018 and fiscal 2017, respectively.

In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, the Company will be eligible to receive from AMAG (i) up to $80,000,000 in specified regulatory milestone payments upon achievement of certain regulatory milestones, and (ii) up to $300,000,000 in sales milestone payments based on achievement of certain annual net sales for all Products in the Territory. On June 4, 2018 the FDA accepted the Vyleesi NDA for filing. The NDA was filed on March 23, 2018. The FDA’s acceptance triggered a $20,000,000 milestone payment to Palatin from AMAG. As a result, the Company recognized $20,000,000 in revenue related to regulatory milestones in fiscal 2018.

On September 6, 2017, we entered into a License Agreement (the “Fosun License Agreement”) with Fosun for exclusive rights to commercialize Vyleesi in the territories of mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R., which provided for $5,000,000 as a one-time non-refundable upfront payment. Pursuant to the Fosun License Agreement with Fosun, $500,000 was withheld in accordance with tax withholding requirements in China and was recorded as an expense during fiscal 2018.

On November 21, 2017, we entered into a License Agreement (the “Kwangdong License Agreement”) with Kwangdong for exclusive rights to commercialize Vyleesi in the Republic of Korea, which provided for a $500,000 one-time refundable upfront payment, which has been recorded as non-current deferred revenue as of June 30, 2018. Pursuant to the License Agreement with Kwangdong, $82,500 was withheld in accordance with tax withholding requirements in South Korea and was recorded as an expense during fiscal 2018.

Research and Development – Research and development expenses were $32,566,217 for fiscal 2018 compared to $45,683,174 for fiscal 2017. These costs primarily relate to our Vyleesi Phase 3 clinical trial program and ancillary studies necessary to file an NDA for Vyleesi for HSDD.

Research and development expenses related to our Vyleesi, PL-3994, PL-8177, MC1r, MC4r and other preclinical programs were $27,449,494 and $41,146,970 in fiscal 2018 and fiscal 2017, respectively. Spending to date has been primarily related to our Vyleesi for the treatment of HSDD program. The decrease in research and development expenses is mainly attributable to the conclusion of Phase 3 clinical trial and development of Vyleesi for HSDD. 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 Vyleesi, PL-8177 and PL-3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which was $5,116,723 and $4,536,204 in fiscal 2018 and fiscal 2017, respectively. The increase in general research and development spending is primarily attributable to additional staffing and secondarily to the recognition of stock-based compensation.

Cumulative spending from inception to June 30, 2018 was approximately $306,900,000 on our Vyleesi program and approximately $130,400,000 on all our other programs (which include PL-3994, PL-8177, other melanocortin receptor agonists, other discovery programs and terminated programs). Due to various risk factors described herein under “Risk Factors,” 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, related net cash inflows will be generated.

General and Administrative – General and administrative expenses, which consist mainly of compensation and related costs, were $8,641,976 for fiscal 2018 compared to $9,610,147 for fiscal 2017. The decrease in general and administrative expenses is primarily attributable to payment for professional services of Greenhill & Co. LLC in fiscal 2017 relating to entering into our license agreement with AMAG and offset by employee related expenses recognized in the year.

Other Income (Expense) – Total other expense, net was $(1,141,351) and $(2,262,039) for fiscal 2018 and fiscal 2017, respectively. For fiscal 2018, we recognized $(1,452,014) of interest expense primarily related to our venture debt offset by $310,663 of investment income. For fiscal 2017, we recognized $(2,288,309) of interest expense primarily related to our venture debt offset by $26,270 of investment income. The decrease in interest expense relates to our paying down of the venture debt.

Income Taxes – Income tax expense was $82,500 in fiscal 2018 compared to $500,000 in fiscal 2017. The fiscal 2018 income tax expense relates to foreign withholding taxes of $582,500 offset by an income tax benefit of $500,000 resulting from the 2017 Tax Act under which Alternative Minimum Tax (“AMT”) credits became refundable and the valuation allowance against the Company’s previously estimated AMT credits was released.

Year Ended June 30, 2017 Compared to the Year Ended June 30, 2016:

Revenue – For fiscal 2017, we recognized $44,723,827 in revenue pursuant to our license agreement with AMAG. For the fiscal year ended June 30, 2016 (“fiscal 2016”), we did not recognize any revenue. As of June 30, 2017, $4,657,577 was received under the agreement and $15,116,822 was included in accounts receivable relating to reimbursable expenses.

Research and Development – Research and development expenses were $45,683,174 for fiscal 2017 compared to $43,071,051 for fiscal 2016. These costs primarily relate to our Vyleesi Phase 3 clinical trial program.

Research and development expenses related to our Vyleesi, PL-3994, MC1r, MC4r and other preclinical programs were $41,146,970 and $39,371,908 in fiscal 2017 and fiscal 2016, respectively. Spending to date was primarily related to our Vyleesi for the treatment of HSDD program. The increase in research and development expenses is mainly attributable to the continued progress of Phase 3 clinical trial and development of Vyleesi for HSDD. 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 Vyleesi and PL-3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which was $4,536,204 and $3,699,143 in fiscal 2017 and fiscal 2016, respectively. The increase in general research and development spending is primarily attributable to additional staffing and secondarily to the recognition of stock-based compensation.

Cumulative spending from inception to June 30, 2017 was approximately $279,000,000 on our Vyleesi program and approximately $125,400,000 on all our other programs (which include PL-3994, PL-8177, other melanocortin receptor agonists, other discovery programs and terminated programs). Due to various risk factors described herein under “Risk Factors,” 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, related net cash inflows will be generated.

General and Administrative – General and administrative expenses, which consist mainly of compensation and related costs, were $9,610,147 for fiscal 2017 compared to $6,179,084 for fiscal 2016. The increase in general and administrative expenses is primarily attributable to payment for professional services of Greenhill & Co. LLC relating to entering into our license agreement with AMAG and secondarily attributable to employee related expenses recognized in the year.

Other Income (Expense) – Total other expense, net was $(2,262,039) and $(2,462,801) for fiscal 2017 and fiscal 2016, respectively. For fiscal 2017, we recognized $(2,288,309) of interest expense primarily related to our venture debt offset by $26,270 of investment income. For fiscal 2016, we recognized $(2,513,027) of interest expense primarily related to our venture debt offset by $50,226 of investment income.

Income Taxes – Income tax expense was $500,000 in fiscal 2017 compared to no income tax expense or benefit in fiscal 2016. The fiscal 2017 income tax expense related to estimated alternative minimum tax (“AMT”) expense based on estimated federal alternative minimum taxable income attributable to the $60,000,000 initial payment from AMAG.

Effects of Inflation

We do not believe that inflation has had a material impact on our business, revenues or operating results during the periods presented.

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 debt and 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;

GMP compliance;

intellectual property rights;

product introduction;

marketing, sales and competition; and

obtaining sufficient capital.

Failure to enter into or successfully perform under 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 fiscal 2018, net cash provided by operating activities was $1,703,103 compared to net cash provided by operating activities of $12,881,527 in fiscal 2017, compared to cash used in operating activities of $47,363,814 in fiscal 2016. The difference in cash provided by operations in fiscal 2018 compared with fiscal 2017 was the result of the initial payment in fiscal 2017 and lower cash receipts relating to the license agreement with AMAG. The difference of cash provided by and cash used in operations in fiscal 2017 compared to fiscal 2016 was primarily the result of the receipt of the initial payment of $60,000,000 relating to the License Agreement with AMAG.

During fiscal 2018, net cash provided by investing activities was $227,549, which consisted of $250,000 of proceeds from maturity of investments offset by $22,451 used for the acquisition of equipment. During fiscal 2017, net cash

provided by investing activities was $991,596, which consisted of $1,124,999 of proceeds from the maturity of investments offset by $133,403 used for the acquisition of equipment. During fiscal 2016, net cash used in investing activities was $1,404,717, consisting primarily of the purchase of investments.

During fiscal 2018, net cash used in financing activities was $4,130,805, which consisted of payments of capital lease obligations of $14,324, payment of withholding taxes related to restricted stock units of $45,165, and payment of debt obligations of $8,000,000, offset by proceeds from the exercise of stock options, and common stock warrants of $2,670,910 and sale of common stock of $1,257,774. During fiscal 2017, net cash provided by financing activities was $18,324,533, which consisted of net proceeds from our underwritten offerings of units consisting of our common stock and warrants in August and December 2016 of $23,856,973 and proceeds from the exercise of warrants of $164,358, offset by $5,696,798 for the payments on notes payable, capital lease payments and the payment of withholding taxes related to restricted stock units. During fiscal 2016, net cash provided by financing activities was $29,471,931, which consisted of a private placement with net proceeds of $19,834,278, a loan of $9,853,885, net of related debt issuance costs, offset by $216,232 for the payment of withholding taxes related to restricted stock units and capital lease payments.

We have incurred cumulative negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Continued operations are dependent upon our ability to complete equity or debt financing activities and enter into licensing or collaboration arrangements. As of June 30, 2018, our cash and cash equivalents were $38,000,171 and our current liabilities were $10,762,965.

We intend to utilize existing capital resources for general corporate purposes and working capital, including Vyleesi, preclinical and clinical development of our MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

We believe that our existing capital resources, together with proceeds received from sales of common stock in our "at-the-market" program (if any), will be adequate to fund our planned operations through at least September 30, 2019. We will need additional funding to complete required clinical trials for our product candidates and development programs other than Vyleesi and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA.

We had net income for fiscal 2018 of $24,702,714, and may attain profitability in the fiscal year ending June 30, 2019 but only if the FDA approves the NDA on Vyleesi for HSDD. We may not sustain profitability in future years, which is dependent on numerous factors, including whether and when development and sales milestones are met, regulatory actions by the FDA and other regulatory bodies, the performance of our licensees, and market acceptance of our products.

We expect to incur significant expenses as we continue our development of natriuretic peptide and MC1r products. These expenses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

We have entered into various contractual obligations and commercial commitments. The following table summarizes our most significant contractual obligations as of June 30, 2018:

	Payments due by Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Facility operating leases	$488,096	$260,960	$227,136	$-	$-
Notes payable, including interest	7,619,134	6,783,212	835,922	-	-
Total contractual obligations	$8,107,230	$7,044,172	$1,063,058	$-	$-

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Table of Contents

Consolidated Financial Statements

The following consolidated financial statements are filed as part of this Annual Report:

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Palatin Technologies, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Palatin Technologies, Inc. and subsidiary (the Company) as of June 30, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficiency), and cash flows for each of the years in the three-year period ended June 30, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended June 30, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of June 30, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated September 13, 2018 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2002.

Philadelphia, Pennsylvania
September 13, 2018

PALATIN
TECHNOLOGIES,
INC.

and Subsidiary

Consolidated
Balance Sheets

	June 30, 2018	June 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$38,000,171	$40,200,324
Available-for-sale investments	-	249,837
Accounts receivable	-	15,116,822
Prepaid expenses and other current assets	513,688	1,011,221
Total current assets	38,513,859	56,578,204
Property and equipment, net	164,035	198,153
Other assets	338,916	56,916
Total assets	$39,016,810	$56,833,273
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	$2,223,693	$1,551,367
Accrued expenses	2,103,021	10,521,098
Notes payable, net of discount	5,948,763	7,824,935
Capital lease obligations	-	14,324
Deferred revenue	-	35,050,572
Other current liabilities	487,488	-
Total current liabilities	10,762,965	54,962,296
Notes payable, net of discount	332,898	6,281,660
Deferred revenue	500,000	-
Other non-current liabilities	456,038	753,961
Total liabilities	12,051,901	61,997,917
Commitments and contingencies (Note 13)		

Stockholders' equity (deficiency):		
Preferred stock of $0.01 par value – authorized 10,000,000 shares:		
Series A Convertible: issued and outstanding 4,030 shares as of June 30, 2018 and June 30, 2017	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares; issued and outstanding 200,554,205 shares as of June 30, 2018 and 160,515,361 as of June 30, 2017	2,005,542	1,605,153
Additional paid-in capital	357,005,233	349,974,538
Accumulated other comprehensive loss	-	(590)
Accumulated deficit	(332,045,906)	(356,743,785)
Total stockholders' equity (deficiency)	26,964,909	(5,164,644)
Total liabilities and stockholders' equity (deficiency)	$39,016,810	$56,833,273

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

PALATIN
TECHNOLOGIES,
INC.

and Subsidiary

Consolidated
Statements of
Operations

	Year Ended June 30,		
	2018	2017	2016
REVENUES			
License and contract	$67,134,758	$44,723,827	$-
OPERATING EXPENSES			
Research and development	32,566,217	45,683,174	43,071,051
General and administrative	8,641,976	9,610,147	6,179,084
Total operating expenses	41,208,193	55,293,321	49,250,135
Income (loss) from operations	25,926,565	(10,569,494)	(49,250,135)
OTHER INCOME (EXPENSE)			
Investment income	310,663	26,270	50,226
Interest expense	(1,452,014)	(2,288,309)	(2,513,027)
Total other expense, net	(1,141,351)	(2,262,039)	(2,462,801)
Income (loss) before income taxes	24,785,214	(12,831,533)	(51,712,936)
Income tax expense	(82,500)	(500,000)	-
NET INCOME (LOSS)	$24,702,714	$(13,331,533)	$(51,712,936)
Basic net income (loss) per common share	$0.12	$(0.07)	$(0.33)
Diluted net income (loss) income per common share	$0.12	$(0.07)	$(0.33)

Weighted average number of common shares outstanding used in computing basic net income (loss) per common share	198,101,060	184,087,719	156,553,534
Weighted average number of common shares outstanding used in computing diluted income (loss) per common share	207,007,558	184,087,719	156,553,534

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

PALATIN TECHNOLOGIES, INC.

and Subsidiary

Consolidated Statements of Comprehensive Income (Loss)

	Year Ended June 30,		
	2018	2017	2016
Net income (loss)	$24,702,714	$(13,331,533)	$(51,712,936)
Other comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale investments	590	1,354	(1,944)
Total comprehensive income (loss)	$24,703,304	$(13,330,179)	$(51,714,880)

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

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Stockholders' Equity (Deficiency)

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balance, June 30, 2015	4,697	$47	57,128,433	$571,284	$303,332,460	$-	$(291,699,316)	$12,204,475
Stock-based compensation	-	-	662,186	6,622	1,836,743	-	-	1,843,365
Sale of common stock units, net of costs	-	-	-	-	19,834,278	-	-	19,834,278
Issuance of warrants on debt	-	-	-	-	305,196	-	-	305,196
Withholding taxes related to restricted stock units	-	-	(123,483)	(1,235)	(57,166)	-	-	(58,401)
Warrant exercises	-	-	10,890,889	108,909	(108,909)	-	-	-
Series A Conversion	(667)	(7)	10,030	100	(93)	-	-	-
Unrealized loss on investments	-	-	-	-	-	(1,944)	-	(1,944)
Net loss	-	-	-	-	-	-	(51,712,936)	(51,712,936)
Balance, June 30, 2016	4,030	40	68,568,055	685,680	325,142,509	(1,944)	(343,412,252)	(17,585,967)
Stock-based compensation	-	-	579,400	5,794	1,751,465	-	-	1,757,259
Sale of common stock	-	-	36,866,097	368,661	23,488,312	-	-	23,856,973

units, net of costs								
Withholding taxes related to restricted stock units	-	-	(75,993)	(760)	(26,328)	-	-	(27,088)
Warrant exercises	-	-	54,577,802	545,778	(381,420)	-	-	164,358
Unrealized gains on investments	-	-	-	-	-	1,354	-	1,354
Net loss	-	-	-	-	-	-	(13,331,533)	(13,331,533)
Balance, June 30, 2017	4,030	40	160,515,361	1,605,153	349,974,538	(590)	(356,743,785)	(5,164,644)
Cumulative effect of accounting change	-	-	-	-	4,835	-	(4,835)	-
Stock-based compensation	-	-	795,041	7,951	3,510,400	-	-	3,518,351
Sale of common stock, net of costs	-	-	1,283,754	12,838	1,244,936	-	-	1,257,774
Withholding taxes related to restricted stock units	-	-	(27,465)	(275)	(20,511)	-	-	(20,786)
Warrant exercises	-	-	37,778,614	377,786	2,133,243	-	-	2,511,029
Option exercises	-	-	208,900	2,089	157,792	-	-	159,881
Unrealized gains on investments	-	-	-	-	-	590	-	590
Net Income	-	-	-	-	-	-	24,702,714	24,702,714
Balance, June 30, 2018	4,030	$40	200,554,205	$2,005,542	$357,005,233	$-	$(332,045,906)	$26,964,909

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

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

	Year Ended June 30,		
	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$24,702,714	$(13,331,533)	$(51,712,936)
Adjustments to reconcile net income (loss) to net cash provided by (used) in operating activities:			
Depreciation and amortization	56,569	33,051	43,052
Non-cash interest expense	175,493	298,790	327,479
Stock-based compensation	3,518,351	1,757,259	1,843,365
Deferred income tax benefit	(500,000)		
Changes in operating assets and liabilities:			
Accounts receivable	15,116,822	(15,116,822)	-
Prepaid expenses and other assets	715,533	308,917	503,785
Accounts payable	672,326	837,477	(392,594)
Accrued expenses	(8,393,698)	2,728,985	1,676,209
Deferred revenue	(34,550,572)	35,050,572	-
Other non-current liabilities	189,565	314,831	347,826
Net cash provided by (used in) operating activities	1,703,103	12,881,527	(47,363,814)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale/maturity of investments	250,000	1,124,999	-
Purchases of investments	-	-	(1,387,022)
Purchases of property and equipment	(22,451)	(133,403)	(17,695)
Net cash provided by (used in) investing activities	227,549	991,596	(1,404,717)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments on capital lease obligations	(14,324)	(27,424)	(25,872)
Payment of withholding taxes related to restricted stock units	(45,165)	(2,708)	(190,360)
Payment on debt obligations	(8,000,000)	(5,666,666)	-
Proceeds from the exercise of stock options	159,881	-	-
Proceeds from exercise of common stock warrants	2,511,029	164,358	-
Proceeds from the sale of common stock and warrants, net of costs	1,257,774	23,856,973	19,834,278
Proceeds from the issuance of notes payable and warrants	-	-	10,000,000
Payment of debt issuance costs	-	-	(146,115)

Net cash (used in) provided by financing activities	(4,130,805)	18,324,533	29,471,931
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,200,153)	32,197,656	(19,296,600)
CASH AND CASH EQUIVALENTS, beginning of year	40,200,324	8,002,668	27,299,268
CASH AND CASH EQUIVALENTS, end of year	$38,000,171	$40,200,324	$8,002,668
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash paid for interest	$1,084,158	$1,676,954	$1,836,743
Issuance of warrants in connection with debt financing	-	-	305,196

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

PALATIN TECHNOLOGIES, INC.
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Notes to Consolidated Financial Statements

(1)
ORGANIZATION

Palatin Technologies, Inc. (“Palatin” or the “Company”) is a specialized biopharmaceutical company developing first-in-class medicines based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our most advanced product candidate is Vyleesi™, the trade name for bremelanotide, a peptide melanocortin receptor 4 (MC4r) agonist, for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (“HSDD”), which is a type of female sexual dysfunction (“FSD”), defined as low desire with associated distress or interpersonal difficulty. A New Drug Application (“NDA”) has been submitted to the U.S. Food and Drug Administration (“FDA”) by our exclusive North American licensee, AMAG Pharmaceuticals, Inc. (“AMAG”) and accepted for filing by the FDA, with an FDA decision on approval expected in the first quarter of calendar 2019.

Vyleesi. Vyleesi is an on demand subcutaneous injectable product for the treatment of HSDD in premenopausal women. Vyleesi is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). In March 2018, our exclusive North American licensee for Vyleesi, AMAG, submitted an NDA to the FDA for Vyleesi for the treatment of HSDD in premenopausal women, which was accepted for filing and review by the FDA. The Prescription Drug User Fee Act (“PDUFA”) date for completion of FDA review of the Vyleesi NDA is March 23, 2019. We have also licensed rights to Vyleesi to Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (“Fosun”) for the territories of the People’s Republic of China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. (collectively, “China”), and Kwangdong Pharmaceutical Co., Ltd. (“Kwangdong”) for the Republic of Korea (“Korea”).

Our Phase 3 studies for HSDD in premenopausal women, called the RECONNECT studies, consisted of two double-blind placebo-controlled, randomized parallel group studies comparing the on demand use of 1.75 mg of Vyleesi versus placebo, in each case, delivered via a subcutaneous auto-injector. Each trial consisted of more than 600 patients randomized in a 1:1 ratio to either the treatment arm or placebo with a 24-week evaluation period. In both clinical trials, Vyleesi met the pre-specified co-primary efficacy endpoints of improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments.

After completing the studies, patients had the option to continue in an open-label safety extension study for an additional 52 weeks. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. In the Phase 3 clinical trials, the most frequent adverse events were nausea, flushing, and headache, which were generally mild-to-moderate in intensity and were transient.

We retain worldwide rights for Vyleesi for HSDD and all other indications outside North America, Korea and China. We are actively seeking potential partners for marketing and commercialization rights for Vyleesi for HSDD outside the licensed territories. However, we may not be able to enter into suitable agreements with potential partners on acceptable terms, if at all.

Melanocortin Receptor Systems. There are five melanocortin receptors, MC1r through MC5r. Modulation of these receptors, through use of receptor-specific agonists, which activate receptor function, or receptor-specific antagonists, which block receptor function, can have significant pharmacological effects. Our new product development activities primarily focus on MC1r agonists, with potential to treat a number of inflammatory and autoimmune diseases such as dry eye disease, also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. We believe that MC1r agonists, including the MC1r agonist peptides we are developing, have broad

anti-inflammatory effects and appear to utilize mechanisms engaged by the endogenous melanocortin system in regulation of the immune system and resolution of inflammatory responses. We are also developing peptides that are active at more than one melanocortin receptor, and MC4r agonists, with potential utility in a number of obesity and metabolic-related disorders, including rare disease and orphan indications.

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements

PL-8177, a selective MC1r agonist peptide, is our lead clinical development candidate for inflammatory bowel diseases, with potential applicability for a number of other diseases. We filed an Investigational New Drug ("IND") application on PL-8177 in late 2017 and have completed subcutaneous dosing of human subjects in a Phase 1 single and multiple ascending dose clinical safety study, with data expected in the fourth quarter of calendar year 2018. We anticipate starting a clinical study with oral dosing of PL-8177 in human subjects in the second half of calendar year 2018, with data expected in the first half of calendar 2019.

PL-8331, a dual MC1r and MC5r peptide agonist, is a preclinical development candidate for treating ocular inflammation. We have initiated IND preclinical enabling activities with PL-8331, and if results are favorable, anticipate filing an IND and initiating clinical trials for treatment of dry eye disease in the second half of calendar year 2019.

We have initiated preclinical programs with MC4r peptides and orally-active small molecules for treatment of rare genetic metabolic and obesity disorders, and if results are favorable, anticipate selecting a lead clinical development candidate and completing IND enabling activities in calendar year 2019.

Natriuretic Peptide Receptor Systems. The natriuretic peptide receptor ("NPR") system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis, heart failure, acute asthma, other pulmonary diseases and hypertension. While the therapeutic potential of modulating this system is well appreciated, development of therapeutic agents has been difficult due, in part, to the short biological half-life of native peptide agonists. We have designed and are developing potential NPR candidate drugs that are selective for one or more different natriuretic peptide receptors, including natriuretic peptide receptor-A ("NPR-A"), natriuretic peptide receptor B ("NPR-B"), and natriuretic peptide receptor C ("NPR-C").

PL-3994 is an NPR-A agonist we developed which has completed Phase 1 clinical safety studies. It has potential utility in treatment of a number of cardiovascular diseases, including genetic and orphan diseases resulting from a deficiency of endogenous active NPR-A. We have ongoing academic collaborations with several institutions with PL-3994.

PL-5028, a dual NPR-A and NPR-C agonist we developed, is in preclinical development for cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis. We have ongoing academic collaborations with several institutions with PL-5028, and seek to enter into a development partnership by the end of calendar year 2019.

Business Risk and Liquidity – Since inception, the Company has incurred negative cash flows from operations, and has expended, and expects to continue to expend, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company had an accumulated deficit as of June 30, 2018 of $332,045,906 and while the Company earned net income for fiscal 2018 of $24,702,714, the Company anticipates incurring significant expenses in the future as a result of spending on its development programs and will require substantial additional financing or revenues to continue to fund its planned developmental activities. To achieve sustained 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 sustained profitability is highly uncertain, and the Company may never be able to achieve profitability on a sustained basis, if at all.

As of June 30, 2018, the Company's cash and cash equivalents, were $38,000,171 and current liabilities were $10,762,965. We intend to utilize existing capital resources for general corporate purposes and working capital, including, preclinical and clinical development of our MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

Management believes that the Company's existing capital resources, together with proceeds received from sales of common stock in the Company's "at-the-market" program (if any), will be adequate to fund the Company's planned operations through at least September 30, 2019. The Company will need additional funding to complete required clinical trials for its other product candidates and, assuming those clinical trials are successful, as to which there can be no assurance, to complete submission of required applications to the FDA. If the Company is unable to obtain approval or otherwise advance in the FDA approval process, the Company's ability to sustain its operations would be materially adversely affected.

PALATIN TECHNOLOGIES, INC.
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Notes to Consolidated Financial Statements

The Company may seek the additional capital necessary to fund its operations through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements. Additional capital that is required by the Company may not be available on reasonable terms, or at all.

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, accounts receivable and investments. The Company's cash and cash equivalents are primarily invested in one money market account sponsored by a large financial institution. For year ended June 30, 2018, the Company reported $62,134,758 in license and contract revenue related to a license agreement with AMAG for Vyleesi for North America ("AMAG License Agreement") (Note 4). In addition, for the year ended June 30, 2018, the Company reported $5,000,000 in license revenue related to a license agreement with Fosun for Vyleesi for China and certain other Asian territories ("Fosun License Agreement") (Note 5). For the year ended June 30, 2017, the Company reported $44,723,827 in contract revenue related to the AMAG License Agreement.

(2)
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 accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts 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 $37,808,099 and $40,019,336 in a money market account at June 30, 2018 and 2017, respectively.

Investments–The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such determinations at each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the intent and ability to hold the securities to maturity. Debt securities for which the Company does not have the intent or ability to hold to maturity are classified as available-for-sale. Held-to-maturity securities are recorded as either short-term or long-term on the balance sheet, based on the contractual maturity date and are stated at amortized cost. Marketable securities that are bought and held principally for the purpose of selling them in the near term are classified as trading securities and are reported at fair value, with unrealized gains and losses recognized in earnings. Debt and marketable equity securities not classified as held-to-maturity or as trading are classified as available-for-sale and are carried at fair market value, with the unrealized gains and losses, net of tax, included in the determination of other comprehensive income (loss).

The fair value of substantially all securities is determined by quoted market prices. The estimated fair value of securities for which there are no quoted market prices is based on similar types of securities that are traded in the market.

Fair Value of Financial Instruments – The Company's financial instruments consist primarily of cash equivalents, accounts receivable, accounts payable and notes payable. Management believes that the carrying values of cash equivalents, available-for-sale investments, accounts receivable and accounts payable are representative of their respective fair values based on the short-term nature of these instruments. Management believes that the carrying amount of its notes payable approximates fair value based on terms of the notes.

Credit Risk – Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. Total cash and cash equivalent balances have exceeded insured balances by the Federal Depository Insurance Company ("FDIC").

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.

PALATIN TECHNOLOGIES, INC.
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Notes to Consolidated Financial Statements

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.

Revenue Recognition – The Company has generated revenue solely through license and collaboration agreements. The Company recognizes revenue in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 605-25, Revenue Recognition for Arrangements with Multiple Elements, which addresses the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting. A delivered item within an arrangement is considered a separate unit of accounting only if both of the following criteria are met:

the delivered item has value to the customer on a stand-alone basis; and

if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in control of the vendor.

Under FASB ASC Topic 605-25, if both of the criteria above are not met, then separate accounting for the individual deliverables is not appropriate.

The Company has determined that it is appropriate to recognize such revenue using the input-based proportional method during the period of Palatin’s development obligations as defined in the license agreement with AMAG (the “AMAG License Agreement”). Refer to Note 4 for additional information.

Under its license agreement with Fosun (the “Fosun License Agreement”) (Note 5), the Company received consideration in the form of an upfront license fee payment and determined that it was appropriate to recognize such consideration as revenue in the first quarter of fiscal 2018, which was the quarter in which the license was granted, since the license has stand-alone value and the upfront payment received by the Company is non-refundable.

Under its license agreement with Kwangdong (the “Kwangdong License Agreement”) (Note 6), the Company received consideration in the form of an upfront license fee payment and has currently determined that it is appropriate to record such consideration as non-current deferred revenue because the upfront payment received by the Company is subject to certain refund provisions.

Revenue resulting from the achievement of development milestones is recorded in accordance with the accounting guidance for the milestone method of revenue recognition.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue on the Company’s consolidated balance sheet. Amounts expected to be recognized as revenue in the next 12 months following the balance sheet date are classified as current liabilities.

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 all 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. If we do not identify services performed for us but not billed by the service-provider, or if we underestimate or overestimate the value of services performed as of a given date, reported expenses will be understated or overstated.

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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 determined using the quoted market price of the Company's common stock on the date of grant and allocated to periods on a straight-line basis, while awards containing a market condition are valued using multifactor Monte Carlo simulations. Compensation costs for awards containing a performance condition are determined using the quoted price of the Company's common stock on the date of grant and allocated to the periods based on the probability of achievement of the performance condition over the service period.

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.

Pursuant to the Fosun License Agreement (Note 5) and Kwangdong License Agreement (Note 6), $500,000 and $82,500, respectively, was withheld in accordance with tax withholding requirements in China and Korea, respectively, and was recorded as an expense during the year ended June 30, 2018. Any potential credit to be received by the Company on its United States tax returns is currently offset by the Company's valuation allowance.

On December 22, 2017, the U.S. government enacted wide-ranging tax legislation, the Tax Cuts and Jobs Act (the "2017 Tax Act"). The 2017 Tax Act significantly revises U.S. tax law by, among other provisions, (a) lowering the applicable U.S. federal statutory corporate income tax rate from 35% to 21%, (b) eliminating or reducing certain income tax deductions, such as deductions for interest expense, executive compensation expenses and certain employee expenses, and (c) repealing the federal alternative minimum tax ("AMT") and providing for the refund of existing AMT credits.

As a result of the enactment of the new corporate income tax rate, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse but continues to maintain a full valuation allowance against its net deferred tax assets. Other provisions enacted include a new provision designed to tax low-taxed income of foreign subsidiaries (i.e., "GILTI") and a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P") from controlled foreign corporations ("CFC"). The Company does not have any foreign subsidiaries, and thus these provisions do not apply.

As a result of the 2017 Tax Act, during the quarter ended December 31, 2017, the Company recorded a tax benefit of $500,000 related to the release of a valuation allowance against an AMT credit (Note 15).

In addition, as a result of the enactment of the new corporate income tax rate, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse but continues to maintain a full valuation allowance against its net deferred tax assets. Other provisions enacted include a new provision designed to tax low-taxed income of foreign subsidiaries (i.e., "GILTI") and a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P") from controlled foreign corporations ("CFC").

The Company does not have any foreign subsidiaries, and thus these provisions do not apply.

Net Income (Loss) per Common Share - Basic and diluted earnings per common share ("EPS") are calculated in accordance with the provisions of FASB ASC Topic 260, Earnings per Share, which includes guidance pertaining to the warrants issued in connection with the July 3, 2012, December 23, 2014, and July 2, 2015 private placement offerings and the August 4, 2016 underwritten offering, that were exercisable for nominal consideration and, therefore, to the extent not yet exercised are considered in the computation of basic and diluted net income (loss) per common share. As of June 30, 2018, all warrants exercisable for nominal value have been converted into common stock.

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 years ended June 30, 2018, 2017 and 2016:

PALATIN TECHNOLOGIES, INC.
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Notes to Consolidated Financial Statements

	Year Ended June 30,		
	2018	2017	2016
Net income (loss)	$24,702,714	$(13,331,533)	$(51,712,936)
Denominator:			
Weighted average common shares outstanding - Basic	198,101,060	184,087,719	156,553,534
Effect of dilutive shares:			
Common stock equivalents arising from stock options, warrants and conversion of preferred stock	6,752,604	-	-
Restriced stock units	2,153,894	-	-
Weighted average common shares outstanding - Diluted	207,007,558	184,087,719	156,553,534
Net income (loss) per common share:			
Basic	$0.12	$(0.07)	$(0.33)
Diluted	$0.12	$(0.07)	$(0.33)

As of June 30, 2018, 2017 and 2016 common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding options and warrants, excluding outstanding warrants exercisable for nominal consideration, and the vesting of restricted stock units amounted in an aggregate of 5,197,592, 40,597,194 and 32,167,737 shares, respectively, being excluded from the weighted average number of common shares outstanding used in computing diluted net income (loss) per common share because they were anti-dilutive during the period or the minimum performance requirements or market conditions had not been met.

(3)
NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending June 30, 2019 and interim periods within that annual period. Early adoption is permitted. The Company has not completed review of the impact of this guidance but does not expect this new guidance to have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments which requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the current guidance as this will require immediate recognition of estimated credit

losses expected to occur over the remaining life of many financial assets. The new guidance will be effective for the Company on July 1, 2020. Early adoption will be available on July 1, 2019. The Company is currently evaluating the effect that ASU No. 2016-13 will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Improvements to Employee Share-Based Payment Accounting, which amended the guidance related to stock compensation. The updated guidance changes how companies account for certain aspects of share-based payment awards to employees, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. Under this guidance, on a prospective basis, companies will no longer record excess tax benefits and certain tax deficiencies as additional paid-in capital. Instead, companies will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. In addition, the guidance eliminates the requirement that excess tax benefits be realized before companies can recognize them. The ASU requires a cumulative-effect adjustment for previously unrecognized excess tax benefits in opening retained earnings in the period of adoption. Effective July 1, 2017, the Company adopted this updated guidance and elected to recognize forfeitures when they occur using a modified retrospective approach. The adoption of ASU No. 2016-09 did not have a material impact on the Company’s consolidated financial statements.

PALATIN TECHNOLOGIES, INC.
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In February 2016, the FASB issued ASU No. 2016-02, Leases, related to the recognition of lease assets and lease liabilities. The new guidance requires lessees to recognize almost all leases on their balance sheet as a right-of-use asset and a lease liability, other than leases that meet the definition of a short- term lease, and requires expanded disclosures about leasing arrangements. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from the current guidance. Lessor accounting is similar to the current guidance, but updated to align with certain changes to the lessee model and the new revenue recognition standard. The new guidance is effective for the Company on July 1, 2019, with early adoption permitted. The Company is currently evaluating the impact that ASU No. 2016-02 will have on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance relates to the recognition and measurement of financial assets and liabilities. The new guidance makes targeted improvements to GAAP impacting equity investments (other than those accounted for under the equity method or consolidated), financial liabilities accounted for under the fair value election, and presentation and disclosure requirements for financial instruments, among other changes. The new guidance is effective for the Company on July 1, 2018, with early adoption prohibited other than for certain provisions. The Company has not completed review of the impact of this guidance but does not expect this new guidance to have a material impact on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes: Balance Sheet Classification of Deferred Taxes, which simplifies the balance sheet classification of deferred taxes. The new guidance requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the new guidance. Effective July 1, 2017, the Company adopted this updated guidance, which did not have a material impact on the Company’s financial position or results of operations because its net deferred tax assets were fully offset by a valuation allowance based on the history of losses incurred.

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. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. With the deferral, the new standard is effective for the Company on July 1, 2018. In addition, in April 2016, the FASB issued ASU No. 2016-10, Identifying Performance Obligations and Licensing, which addresses various issues associated with identifying performance obligations, licensing of intellectual property, royalty considerations, and other matters. ASU No. 2016-10 is effective in connection with ASU No. 2014-09. The two permitted transition methods under ASU 2014-09 are the full retrospective method, in which case the new standard would be applied to each prior period presented and the cumulative effect of applying the standard would be recognized as of the earliest period reported, or the modified retrospective method, in which case the cumulative effect of applying the new standard would be recognized as of the date of initial application.

The Company has elected to adopt the new standard using the modified retrospective approach. The Company has completed its review to assess the impact to its consolidated financial statements, including an assessment of the Company’s three key contracts. Based on the review of these contracts, the Company expects the effect of initially applying the new standard to result in a decrease to the opening balance of accumulated deficit of $500,000 as a result of recognition of revenue deferred as of June 30, 2018. The Company is continuing its assessment of the impact over

its financial reporting disclosures.

(4)
AGREEMENT WITH AMAG

On January 8, 2017, the Company entered into the AMAG License Agreement. Under the terms of the AMAG License Agreement, the Company granted to AMAG (i) an exclusive license in all countries of North America (the "Territory"), with the right to grant sub-licenses, to research, develop and commercialize products containing Vyleesi (each a Product, and collectively, Products), (ii) a non-exclusive license in the Territory, with the right to grant sub-licenses, to manufacture Products, and (iii) a non-exclusive license in all countries outside the Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Products.

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Following the satisfaction of certain conditions to closing, the license agreement became effective on February 2, 2017. On that date, AMAG paid the Company $60,000,000 as a one-time initial payment. Pursuant to the terms of and subject to the conditions in the AMAG License Agreement, AMAG was required to reimburse the Company up to an aggregate amount of $25,000,000 for reasonable, documented, direct out-of-pocket expenses incurred by the Company following February 2, 2017, in connection with the development and regulatory activities necessary to file an NDA for Vyleesi for HSDD in the United States related to Palatin's development obligations.

The Company has determined there is no stand-alone value for the license, and that the license and the reimbursable direct out-of-pocket expenses, pursuant to the terms of the License Agreement, represent a combined unit of accounting which totals $85,000,000. The Company recognized revenue of the combined unit of accounting over the arrangement using the input-based proportional method as the Company completed its development obligations. For the years ended June 30, 2018 and 2017, the Company recognized $42,134,758 and $44,723,827, respectively, as license and contract revenue which included additional billings for AMAG related Vyleesi costs of $1,151,243 and $707,342 in fiscal 2018 and fiscal 2017, respectively.

In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, the Company will be eligible to receive from AMAG (i) up to $80,000,000 in specified regulatory milestone payments upon achievement of certain regulatory milestones, and (ii) up to $300,000,000 in sales milestone payments based on achievement of certain annual net sales for all Products in the Territory. On June 4, 2018 the FDA accepted the Vyleesi NDA for filing. The NDA was filed on March 23, 2018. The FDA's acceptance triggered a $20,000,000 million milestone payment to Palatin from AMAG. As a result, the Company recognized $20,000,000 in revenue related to regulatory milestones for the year ended June 30, 2018.

AMAG is also obligated to pay the Company tiered royalties on annual net sales of Products, on a product-by-product basis, in the Territory ranging from the high single-digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis until the latest to occur of (i) the earliest date on which there are no valid claims of the Company's patent rights covering such Product in such country, (ii) the expiration of the regulatory exclusivity period for such Product in such country and (iii) ten years following the first commercial sale of such Product in such country. Such royalties are subject to reductions in the event that: (a) AMAG must license additional third-party intellectual property in order to develop, manufacture or commercialize a Product, or (b) generic competition occurs with respect to a Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to the Company. After the expiration of the applicable royalties for any Product in a given country, the license for such Product in such country will become a fully paid-up, royalty-free, perpetual and irrevocable license.

The Company engaged Greenhill & Co. LLC ("Greenhill") as the Company's sole financial advisor in connection with a potential transaction with respect to Vyleesi. Under the engagement agreement with Greenhill, the Company was obligated to pay Greenhill a fee equal to 2% of all proceeds and consideration paid to the Company by AMAG in connection with the AMAG License Agreement, subject to a minimum fee of $2,500,000. The minimum fee of $2,500,000, less a credit of $50,000 for an advisory fee previously paid by the Company, was paid to Greenhill upon the closing of the licensing transaction. This amount will be credited toward amounts that become due to Greenhill in the future, provided that the aggregate fee payable to Greenhill will not be less than 2% of all proceeds and consideration paid to the Company by AMAG in connection with the AMAG License Agreement. The Company will pay Greenhill an aggregate total of 2% of all proceeds and consideration paid to the Company by AMAG in connection with the License Agreement, including future milestone and royalty payments, after crediting the $2,500,000 that was paid to Greenhill upon entering into the AMAG License Agreement. The Company also

reimbursed Greenhill $7,263 for certain expenses incurred in connection with its advisory services.

Pursuant to the License Agreement, the Company has assigned to AMAG the Company's manufacturing and supply agreements with Catalent Belgium S.A. to perform fill, finish and packaging of Vyleesi.

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(5)
AGREEMENT WITH FOSUN:

On September 6, 2017, the Company entered into the Fosun License Agreement for exclusive rights to commercialize Vyleesi in China. Under the terms of the agreement, the Company received $4,500,000 in October 2017, which consisted of an upfront payment of $5,000,000 less $500,000 that was withheld in accordance with tax withholding requirements in China and recorded as an expense during the year ended June 30, 2018. The Company will receive a $7,500,000 milestone payment when regulatory approval in China is obtained, provided that a commercial supply agreement for Vyleesi has been entered into. Palatin has the potential to receive up to $92,500,000 in additional sales related milestone payments and high single-digit to low double-digit royalties on net sales in the licensed territory. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territory will be the sole responsibility of Fosun.

(6)
AGREEMENT WITH KWANGDONG:

On November 21, 2017, the Company entered into the Kwangdong License Agreement for exclusive rights to commercialize Vyleesi in Korea. Under the terms of the agreement, the Company received $417,500 in December 2017, consisting of an upfront payment of $500,000, less $82,500, which was withheld in accordance with tax withholding requirements in Korea and recorded as an expense during the year ended June 30, 2018. Based upon certain refund provisions, the upfront payment has been recorded as non-current deferred revenue at June 30, 2018. The Company will receive a $3,000,000 milestone payment based on the first commercial sale in Korea. Palatin has the potential to receive up to $37,500,000 in additional sales related milestone payments and mid-single-digit to low double-digit royalties on net sales in the licensed territory. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territory will be the sole responsibility of Kwangdong.

(7)
PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	June 30, 2018	June 30, 2017
Clinical study costs	$145,994	$657,069
Insurance premiums	42,605	182,966
Other	325,089	171,186
	$513,688	$1,011,221

(8)
INVESTMENTS

The following summarizes the carrying value of our available-for-sale investments, which consist of corporate debt securities:

	June 30, 2018	June 30, 2017
Cost	$-	$1,387,022
Matured investments	-	(1,124,999)
Amortization of premium	-	(11,596)
Gross unrealized loss	-	(590)
Fair value	$-	$249,837

(9)
FAIR VALUE MEASUREMENTS

The fair value of cash equivalents is 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.

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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)
June 30, 2018:				
Money Market Account	$37,808,099	$37,808,099	$-	$-
June 30, 2017:				
Money Market Account	$40,019,336	$40,019,336	$-	$-

(10)
PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consists of the following:

	June 30, 2018	June 30, 2017
Office equipment	$1,193,162	$1,180,210
Laboratory equipment	558,205	548,706
Leasehold improvements	751,226	751,226
	2,502,593	2,480,142
Less: Accumulated depreciation and amortization	(2,338,558)	(2,281,989)
	$164,035	$198,153

The aggregate cost of assets acquired under capital leases was $146,115 as of both June 30, 2018 and 2017. Accumulated amortization associated with assets acquired under capital leases was $122,115 and $106,115 as of June 30, 2018 and 2017, respectively.

(11)
ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30,	June 30,

	2018	2017
Clinical study costs	$983,410	$9,138,827
Other research related expenses	590,236	217,307
Professional services	297,731	434,768
Other	231,644	730,196
	$2,103,021	$10,521,098

(12)
NOTES PAYABLE:

Notes payable consist of the following:

	June 30, 2018	June 30, 2017
Notes payable under venture loan	$6,333,334	$14,333,334
Unamortized related debt discount	(33,535)	(143,524)
Unamortized debt issuance costs	(18,138)	(83,215)
Notes payable	6,281,661	14,106,595
Less: current portion	5,948,763	7,824,935
Long-term portion	$332,898	$6,281,660

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On December 23, 2014, the Company closed on a $10,000,000 venture loan which was led by Horizon Technology Finance Corporation (“Horizon”). The debt facility is a four-year senior secured term loan that bears interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50%, and provides for interest-only payments for the first eighteen months followed by monthly payments of principal of $333,333 plus accrued interest through January 1, 2019. The lenders also received five-year immediately exercisable Series D 2014 warrants to purchase 666,666 shares of common stock exercisable at an exercise price of $0.75 per share. The Company recorded a debt discount of $267,820 equal to the fair value of these warrants at issuance, which is being amortized to interest expense over the term of the related debt. This debt discount is offset against the note payable balance and included in additional paid-in capital on the Company’s balance sheet at June 30, 2018 and June 30, 2017. In addition, a final incremental payment of $500,000 is due on January 1, 2019, or upon early repayment of the loan. This final incremental payment is being accreted to interest expense over the term of the related debt and is included in other current liabilities on the consolidated balance sheet as of June 30, 2018. The Company incurred $209,367 of costs in connection with the loan. These costs were capitalized as deferred financing costs and are offset against the note payable balance. These debt issuance costs are being amortized to interest expense over the term of the related debt.

On July 2, 2015, the Company closed on a $10,000,000 venture loan led by Horizon. The debt facility is a four-year senior secured term loan that bears interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50% and provides for interest-only payments for the first eighteen months followed by monthly payments of principal of $333,333 plus accrued interest through August 1, 2019. The lenders also received five-year immediately exercisable Series G warrants to purchase 549,450 shares of the Company’s common stock exercisable at an exercise price of $0.91 per share. The Company has recorded a debt discount of $305,196 equal to the fair value of these warrants at issuance, which is being amortized to interest expense over the term of the related debt. This debt discount is offset against the note payable balance and is included in additional paid-in capital on the Company’s balance sheet at June 30, 2018 and June 30, 2017. In addition, a final incremental payment of $500,000 is due on August 1, 2019, or upon early repayment of the loan. This final incremental payment is being accreted to interest expense over the term of the related debt and is included in other non-current liabilities on the consolidated balance sheet as of June 30, 2018. The Company incurred $146,115 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and are offset against the note payable balance. These debt issuance costs are being amortized to interest expense over the term of the related debt.

The Company’s obligations under the 2015 amended and restated loan agreement, which includes both the 2014 venture loan and the 2015 venture loan, are secured by a first priority security interest in substantially all of its assets other than its intellectual property. The Company also has agreed to specified limitations on pledging or otherwise encumbering its intellectual property assets. The 2015 amended and restated loan agreement includes customary affirmative and restrictive covenants, but does not include any covenants to attain or maintain specified financial metrics. The loan agreement includes customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan agreement. As of June 30, 2018, the Company was in compliance with all of its loan covenants. Scheduled future principal payments related to notes payable as of June 30, 2018 are as follows:

Year Ending June 30,	
2019	$6,000,000

2020	333,334
	6,333,334
Less: Unamortized debt discount and issuance costs	(51,673)
Net	$6,281,661

(13)
COMMITMENTS AND CONTINGENCIES

Operating Leases – The Company currently leases facilities under two non-cancelable operating leases. The lease on our corporate offices was renewed effective July 1, 2015 and expires on June 30, 2020 and in June 2016 we entered into a lease for approximately 1,700 square feet of laboratory space which expires in August 2019. Future minimum lease payments under these leases are as follows:

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Year Ending June 30,

2019	$260,960
2020	227,136
	$488,096

For the years ended June 30, 2018, 2017 and 2016, rent expense was $292,411, $261,580 and $256,642 respectively.

Employment Agreements – The Company has employment agreements with two executive officers which provide a stated annual compensation amount, subject to annual increases, and annual bonus compensation in an amount to be approved by the Company's Board of Directors. Each agreement allows the Company or the employee to terminate the agreement in certain circumstances. In some circumstances, early termination by the Company may result in severance pay to the employee for a period of 18 to 24 months at the salary then in effect, continuation of health insurance premiums over the severance period and immediate vesting of all stock options and restricted stock units. Termination following a change in control will result in a lump sum payment of one and one-half to two times the salary then in effect and immediate vesting of all stock options and restricted stock units.

Employee Retirement Savings Plan – The Company maintains a defined contribution 401(k) plan for the benefit of its employees. The Company currently matches a portion of employee contributions to the plan. For the years ended June 30, 2018, 2017 and 2016, Company contributions were $166,962, $199,264 and $138,184, respectively.

Contingencies – The Company accounts for litigation losses in accordance with ASC 450-20, Loss Contingencies. Under ASC 450-20, loss contingency provisions are recorded for probable losses when management is able to reasonably estimate the loss. Any outcome upon settlement that deviates from the Company's best estimate may result in additional expense or in a reduction in expense in a future accounting period. The Company records legal expenses associated with such contingencies as incurred.

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. The Company is not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

(14)
STOCKHOLDERS' EQUITY (DEFICIENCY)

Series A Convertible Preferred Stock – As of June 30, 2018, 4,030 shares of Series A Convertible Preferred Stock were outstanding. Each share of Series A Convertible Preferred Stock is convertible at any time, at the option of the holder, into the number of shares of common stock equal to $100 divided by the Series A Conversion Price. As of June 30, 2018, the Series A Conversion Price was $6.65, so each share of Series A Convertible Preferred Stock is currently convertible into approximately 15.0 shares of common stock. The Series A Conversion Price is subject to adjustment, under certain circumstances, upon the sale or issuance of common stock for consideration per share less than either (i) the Series A Conversion Price in effect on the date of such sale or issuance, or (ii) the market price of the common stock as of the date of such sale or issuance. The Series A Conversion Price is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which will result in an increase or decrease in the number of shares of common stock outstanding. Shares of Series A Convertible

Preferred Stock have a preference in liquidation, including certain merger transactions, of $100 per share, or $403,000 in the aggregate as of June 30, 2018. Additionally, the Company may not pay a dividend or make any distribution to holders of any class of stock unless the Company first pays a special dividend or distribution of $100 per share to holders of the Series A Convertible Preferred Stock.

Financing Transactions – On April 20, 2018, the Company entered into an equity distribution agreement (the "Equity Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company may, from time to time, sell shares of the Company's common stock at market prices by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company will pay Canaccord 3.0% of the gross proceeds as a commission. Between April 20, 2018 and June 30, 2018, a total of 1,283,754 shares of common stock were sold through Canaccord under the Equity Distribution Agreement for net proceeds of $1,257,773 after payment of commission fees of $43,385 and other related expenses of $145,000. The Company has no obligation to sell any shares under the Equity Distribution Agreement and may at any time suspend solicitation and offers under the Equity Distribution Agreement.

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On December 6, 2016, the Company closed on an underwritten public offering of units, with each unit consisting of a share of common stock and a Series J warrant to purchase 0.50 of a share of common stock. Gross proceeds of the offering were $16,500,000, with net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, of $15,386,076. The Company issued 25,384,616 shares of common stock and Series J warrants to purchase 12,692,310 shares of common stock at an initial exercise price of $0.80 per share, which warrants are exercisable immediately upon issuance and expire on the fifth anniversary of the date of issuance. The Series J warrants are subject to a limitation on their exercise if the holder and its affiliates would beneficially own more than 9.99%, or 4.99% for certain holders, of the total number of the Company's shares of common stock following such exercise.

On August 4, 2016, the Company closed on an underwritten offering of units, with each unit consisting of a share of common stock and a Series H warrant to purchase 0.75 of a share of common stock. Investors whose purchase of units in the offering would result in them beneficially owning more than 9.99% of the Company's outstanding common stock following the completion of the offering had the opportunity to acquire units with Series I prefunded warrants substituted for any common stock they would have otherwise acquired. Gross proceeds of the offering were $9,225,000, with net proceeds to the Company, after deducting offering expenses, of $8,470,897. The Company issued 11,481,481 shares of common stock and ten-year prefunded Series I warrants to purchase 2,218,045 shares of common stock at an exercise price of $0.01, together with Series H warrants to purchase 10,274,646 shares of common stock at an exercise price of $0.70 per share.

The Series I warrants were exercisable immediately upon issuance and were exercised during the year ended June 30, 2017. The Series H warrants are exercisable at an initial exercise price of $0.70 per share, are exercisable commencing six months following the date of issuance and expire on the fifth anniversary of the date of issuance. The Series H warrants are subject to a limitation on their exercise if the holder and its affiliates would beneficially own more than 9.99% of the total number of the Company's shares of common stock following such exercise.

On July 2, 2015, the Company closed on a private placement of Series E warrants to purchase 21,917,808 shares of common stock and Series F warrants to purchase 2,191,781 shares of common stock. Certain funds managed by QVT Financial LP ("QVT") invested $5,000,000 and another accredited investment fund invested $15,000,000. The funds paid $0.90 for each Series E warrant and $0.125 for each Series F warrant, resulting in gross proceeds to the Company of $20,000,000, with net proceeds, after deducting estimated offering expenses, of approximately $19,834,278.

The Series E warrants, which would be exercised on a cashless basis, were exercisable immediately upon issuance at an initial exercise price of $0.01 per share, and the exercise of all Series E warrants was completed during the year ended June 30, 2018. The Series F warrants are exercisable at an initial exercise price of $0.91 per share, exercisable immediately upon issuance and expire on the fifth anniversary of the date of issuance. The Series F warrants are subject to a limitation on their exercise if the holder and its affiliates would beneficially own more than 9.99% of the total number of the Company's shares of common stock following such exercise.

Outstanding Stock Purchase Warrants – As of June 30, 2018, the Company had outstanding warrants exercisable for shares of common stock as follows:

Shares of Common	Exercise Price per	Latest Termination Date

Stock	Share	
666,666	0.75	December 23, 2019
2,191,781	0.91	July 2, 2020
549,450	0.91	July 2, 2020
10,274,646	0.70	August 4, 2021
25,000	0.70	August 4, 2021
9,696,503	0.80	December 6, 2021
23,404,046		

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During the year ended June 30, 2018, the Company received $2,396,646 and $114,383, respectively, and issued 2,995,807 shares of common stock pursuant to the exercise of warrants at an exercise price of $0.80 per share and issued 11,438,356 shares of common stock pursuant to the exercise of warrants at an exercise price of $0.01 per share. The Company also issued 23,344,451 shares of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of $0.01 per share. As of June 30, 2018, there were no warrants outstanding at an exercise price of $0.01 per share.

During the year ended June 30, 2017, the Company issued 38,141,991 shares of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of $0.01 per share, and during the year ended June 30, 2017, the Company received $164,358 and issued 16,435,811 shares of common stock pursuant to the exercise of warrants at an exercise price of $0.01 per share. During the year ended June 30, 2016, the Company issued 10,890,889 shares of common stock pursuant to the cashless exercise provisions of warrants at an exercise price of $0.01.

On October 31, 2016, in connection with a contract for financial advisory services, the Company issued to each of PSL Business Development Consulting and SARL Avisius, or their permitted designees, as partial consideration for services, a warrant to purchase up to 12,500 shares of the Company’s common stock at an exercise price of $0.70 per share. The warrants are exercisable at any time, and expire on August 4, 2021. The Company recorded stock-based compensation related to these stock warrants of $6,885 for the year ended June 30, 2017.

Stock Plan – The Company’s 2011 Stock Incentive Plan was approved by the Company’s stockholders at the annual meeting of stockholders held in May 2011 and amended at the annual meeting of stockholders held on June 8, 2017 and again at the annual meeting of stockholders held on June 26, 2018. The 2011 Stock Incentive Plan provides for incentive and nonqualified stock option grants, restricted stock unit awards and other stock-based awards to employees, non-employee directors and consultants for up to 32,500,000 shares of common stock. The 2011 Stock Incentive Plan is administered under the direction of the Board of Directors, which may specify grant terms and recipients. Options granted by the Company generally expire ten years from the date of grant and generally vest over three to four years. The Company’s former 2005 Stock Plan was terminated and replaced by the 2011 Stock Incentive Plan, and shares of common stock that were available for grant under the 2005 Stock Plan became available for grant under the 2011 Stock Incentive Plan. No new awards can be granted under the 2005 Stock Plan, but awards granted under the 2005 Stock Plan remain outstanding in accordance with their terms. As of June 30, 2018, 7,559,248 shares were available for grant under the 2011 Stock Incentive Plan.

The Company has outstanding options that were granted under the 2005 Stock Plan. The Company expects to settle option exercises under any of its plans with authorized but currently unissued shares.

The following table summarizes option activity and related information for the years ended June 30, 2018, 2017 and 2016:

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	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Outstanding - July 1, 2015	5,130,230	1.46	7.3	
Granted	355,000	0.54		
Forfeited	(170,550)	0.80		
Expired	(52,940)	22.53		
Outstanding - June 30, 2016	5,261,740	1.21	6.2	
Granted	4,119,000	0.46		
Forfeited	(410,388)	1.12		
Expired	(43,220)	22.59		
Outstanding - June 30, 2017	8,927,132	0.76	7.5	

Granted	4,182,550	0.90
Forfeited	(39,500)	1.70
Exercised	(208,900)	0.77
Expired	(85,820)	6.95

Outstanding - June 30, 2018	12,775,462	$0.76	7.7	$3,115,515
Exercisable at June 30, 2018	6,163,850	$0.79	6.0	$1,460,394
Expected to vest at June 30, 2018	6,611,612	$0.54	9.2	$1,651,121

For the years ended June 30, 2018, 2017 and 2016, the fair value of option grants was estimated at the grant date using the Black-Scholes model or a multi-factor Monte Carlo simulation. The Company's weighted average assumptions for the years ended June 30, 2018, 2017 and 2016 were as follows:

	2018	2017	2016
Risk-free interest rate	1.8%	1.7%	1.4%
Volatility factor	52.6%	75.0%	73.5%
Dividend yield	0%	0%	0%
Expected option life (years)	4.4	6.2	5.7
Weighted average grant date fair value	$0.58	$0.27	$0.35

Expected volatilities are based on the Company's historical volatility. The expected term of options is based upon the simplified method, which represents the average of the vesting term and the contractual term. The risk-free interest rate is based on U.S. Treasury yields for securities with terms approximating the expected term of the option.

For the years ended June 30, 2018, 2017 and 2016 the Company recorded stock-based compensation related to stock options of $1,131,895, $547,953, and $545,641, respectively. As of June 30, 2018, there was $2,706,207 of unrecognized compensation cost related to unvested options, which is expected to be recognized over a weighted-average period of 2.9 years.

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In June 2018, the Company granted 987,000 options to its executive officers, 262,550 options to its employees and 224,000 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 $659,159, $175,342 and $139,666, respectively, over the vesting period.

In December 2017, the Company granted 1,200,000 options to its executive officers and 225,000 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The fair value of these options was $691,171 and $126,130, respectively. The Company is amortizing the fair value of these options over a 48-month vesting period for its executive officers and over a 36-month vesting period for its non-employee directors.

Also, in December 2017, the Company granted 1,075,000 and 125,000 performance-based options to its executive officers and employees, respectively, which vest during a performance period ending on December 31, 2020, if and upon either i) as to 100% of the target number of shares upon achievement of a closing price for the Company's common stock equal to or greater than $1.50 per share for 20 consecutive trading days, which is considered a market condition; or ii) as to thirty percent (30%) of the target number of shares, upon the acceptance for filing by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is considered a performance condition; iii) as to fifty percent (50%) of the target number of shares, upon the approval by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is also considered a performance condition; iv) as to twenty percent (20%) of the target number of shares, upon entry into a licensing agreement during the performance period for the commercialization of Vyleesi for FSD in selected countries, which is also considered a performance condition. The fair value of these options was $602,760. The Company is amortizing the fair value over the derived service period of 1.1 years or upon the attainment of the performance condition. Pursuant to the FDA acceptance of the NDA filing of Vyleesi, 30% of the target number of options vested in June 2018.

In September 2017, the Company granted 54,000 options to a newly appointed non-employee director under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $18,176 over a 48-month vesting period.

During the year ended June 30, 2018, the Company also granted 30,000 options to three new hires under the Company's 2011 Stock Incentive Plan. The fair value of these options was $14,505. The Company is amortizing the fair value of these options over a 48-month vesting period.

In June 2017, the Company granted 1,797,000 options to its executive officers, 780,000 options to its employees and 378,000 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 $445,533, $194,689 and $89,220, respectively, over the vesting period.

In September 2016, the Company granted 828,000 options to its executive officers and 336,000 options to its employees under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of the options vesting over a 48-month period, consisting of 595,000 options granted to its executive officers and all options granted to its employees, of $188,245 and $106,303, respectively, over the vesting period. The remaining 233,000 options granted to its executive officers vested 12 months from the date of grant, and the Company amortized the fair value of these options of $67,160 over this vesting period.

In June 2016, the Company granted 262,500 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company amortized the fair value of these options of $81,435 over the vesting period and they were fully vested as of June 30, 2017.

During the year-ended June 30, 2016, the Company granted an aggregate 92,500 options to certain employees under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of $41,470 over the vesting period.

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Unless otherwise stated, 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 – The following table summarizes restricted stock award activity for the years ended June 30, 2018, 2017 and 2016:

	2018	2017	2016
Outstanding at beginning of year	5,209,617	2,665,768	1,028,017
Granted	4,914,550	3,192,000	2,302,500
Forfeited	(5,250)	(68,751)	(2,563)
Vested	(795,041)	(579,400)	(662,186)
Outstanding at end of year	9,323,876	5,209,617	2,665,768

For the years ended June 30, 2018, 2017 and 2016 the Company recorded stock-based compensation related to restricted stock units of $2,386,456, $1,202,421, and $1,297,724, respectively.

In June 2018, the Company granted 659,000 restricted stock units to its executive officers, 262,550 restricted stock units to its employees and 224,000 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 $659,000, $262,550, and $224,000, respectively, over the vesting period.

In December 2017, the Company granted 1,200,000 restricted stock units to its executive officers, 225,000 restricted stock units to its non-employee directors and 545,000 restricted stock units to its employees under the Company's 2011 Stock Incentive Plan. The fair value of these restricted stock units was $1,020,000, $191,250 and $463,250, respectively. For executive officers and employees, the restricted stock units vest 25% on the first, second, third and fourth anniversary dates from the date of grant. For non-employee directors, the restricted stock units vest 33 1/3% on the first, second and third anniversary dates from the date of grant.

Also, in December 2017, the Company granted 1,075,000 performance-based restricted stock units to its executive officers and 670,000 performance-based restricted stock units to other employees which vest during a performance period, ending on December 31, 2020, if and upon either i) as to 100% of the target number of shares upon achievement of a closing price for the Company's common stock equal to or greater than $1.50 per share for 20 consecutive trading days, which is considered a market condition; or ii) as to thirty percent (30%) of the target number of shares, upon the acceptance for filing by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is considered a performance condition; iii) as to fifty percent (50%) of the target number of shares, upon the approval by the FDA of an NDA for Vyleesi for HSDD in premenopausal women during the performance period, which is also considered a performance condition; iv) as to twenty percent (20%) of the target number of shares, upon entry into a licensing agreement during the performance period for the commercialization of Vyleesi for FSD in at least two of the following geographic areas (a) four or more countries in Europe, (b) Japan, (c) two or more countries in Central and/or South America, (d) two or more countries in Asia, excluding Japan and China, and (e) Australia, which is also considered a performance condition. The fair value of these awards was $913,750 and $569,500, respectively. The Company is amortizing the fair value over the derived service period of 1.1 years or upon the attainment of the performance condition. Pursuant to the FDA acceptance of the NDA filing for Vyleesi, 30% of the target number of shares vested in June 2018.

In September 2017, the Company granted 54,000 restricted stock units to a newly appointed non-employee director under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of $27,000 over a 48-month vesting period.

In June 2017, the Company granted 1,140,000 restricted stock units to its executive officers, 780,000 restricted stock units to its employees and 378,000 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 $421,800, $288,600, and $139,860, respectively, over the vesting period.

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In September 2016, the Company granted 558,000 restricted stock units to its executive officers, 415,000 of which vest over 24 months and 143,000 of which vested at 12 months, and 336,000 restricted stock units to its employees under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of the restricted stock units of $284,580, and $171,360, respectively, over the vesting periods.

In June 2016, the Company granted 262,500 restricted stock units to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company amortized the fair value of these options of $131,250, over the vesting period.

In December 2015, the Company granted 625,000 performance-based restricted stock units to its executive officers and 200,000 performance-based restricted stock units to its employees under the Company's 2011 Stock Incentive Plan, which vested during the performance period, ended December 31, 2017, upon the earlier of: i) achievement of a closing price for the Company's common stock equal to or greater than $1.20 per share for 20 consecutive trading days, which was considered a market condition, or ii) entering into a collaboration agreement (U.S. or global) of Vyleesi for FSD, which was considered a performance condition. This performance condition was deemed met as of February 2, 2017, the effective date of the License Agreement on Vyleesi with AMAG. Prior to meeting the performance condition, the Company determined that it was not probable of achievement on the date of grant since meeting the condition was outside the control of the Company. The fair value of these awards, as calculated under a multifactor Monte Carlo simulation, was $338,250 and was recognized over the derived service period which was through December 2016. Upon the achievement of the performance condition, which occurred in the three-month period ended March 31, 2017 the grant date fair value was utilized and an incremental $222,075 was recognized as stock-based compensation expense during the three months ended March 31, 2017. Also, in December 2015, the Company granted 625,000 restricted stock units to its executive officers, 340,000 restricted stock units to its non-employee directors and 200,000 restricted stock units to its employees under the Company's 2011 Stock Incentive Plan. For executive officers and employees, the restricted stock units vest 25% on the date of grant and 25% on the first, second and third anniversary dates from the date of grant. For non-employee directors, the restricted stock units vested 50% on the first and second anniversary dates from the date of grant. The Company is amortizing the fair value of these restricted stock units of $425,000, $231,200 and $136,000, respectively, over the vesting period.

Unless otherwise stated, time-based restricted stock units granted to the Company's executive officers, employees and non-employee directors vest over 24 months, 48 months and 12 months, respectively.

In connection with the vesting of restricted share units during the years ended June 30, 2018, 2017 and 2016, the Company withheld 27,465, 75,993 and 123,483 shares with aggregate values of $20,786, $27,088 and $58,401 respectively, in satisfaction of minimum tax withholding obligations.

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INCOME TAXES

For fiscal 2018, the Company recorded income tax expense of $82,500, which consisted of $500,000 that was withheld in accordance with tax withholding requirements in China related to our Fosun License Agreement (Note 5) and $82,500, which was withheld in accordance with tax withholding requirements in Korea related to our Kwangdong License Agreement (Note 6). The total income tax expense of $582,500 was offset by an income tax benefit of $500,000, which resulted from the 2017 Tax Act, under which AMT credits became refundable, and therefore a $500,000 benefit related to the release of a valuation allowance against an AMT credit was recorded during the quarter ended December 2017. The Company's June 30, 2017 tax return was filed during the quarter ended

March 31, 2018 and the Company did not incur an AMT liability. As a result, as of June 30, 2018, the Company has a current income tax receivable of $218,000 and a long-term income tax receivable of $282,000 from estimated fiscal 2018 AMT that can be refunded in the future.

For fiscal 2017, the Company incurred $500,000 of estimated federal AMT expense based on estimated federal alternative minimum taxable income attributable to the $60,000,000 initial payment from AMAG. For fiscal 2016 the Company had no income tax expense because of operating losses or a tax benefit from the sale of New Jersey state net operating loss carryforwards on account that it reached the state limits on the sale of New Jersey state net operating loss carryforwards and tax credits.

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Deferred tax assets and liabilities are determined based on the estimated future tax effect of differences between the financial statement and tax reporting basis of assets and liabilities, as well as for, net operating loss carryforwards and research and development credit carryforwards, given the provisions of existing tax laws.

As a result of the enactment of the new corporate income tax rate, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse, but continues to maintain a full valuation allowance against its deferred tax assets.

As of June 30, 2018, the Company had state net operating loss carryforwards of approximately $118,309,000, which will expire, if not utilized, between 2030 and 2037, federal net operating loss carryforwards of approximately $100,439,000, federal research and development credits of approximately $5,649,000, which expire, if not utilized, between 2020 and 2038, and foreign tax credits of $582,500, which expire, if not utilized, in 2028.

The Tax Reform Act of 1986 (the “Act”) provides for limitation on the use of these net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company’s ability to utilize these carryforwards. Since its inception, the Company has completed several financings and sales of common stock which has resulted in multiple ownership changes defined by Section 382 of the Act. Accordingly, the Company’s ability to utilize the aforementioned carryforwards are subject to limitation under Section 382.

The Company does have adequate levels of available net operating loss carryforwards that are not subject to limitation under Section 382 to offset taxable income during the tax year ended June 30, 2018. If the Company undergoes a future ownership change or as it completes its Section 382 limitation assessment, any unutilized carryforwards that were not previously subject to a Section 382 limitation may become subject to limitation which may result in a significant limitation and loss of net operating loss carryforwards.

Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, the Company may not be able to take full advantage of these carryforwards for federal income tax purposes. Accordingly, a portion of the carryforwards may expire unutilized.

The Company’s net deferred tax assets are as follows:

	June 30, 2018	June 30, 2017
Net operating loss carryforwards	$29,504,000	$103,845,000
Research and development and AMT tax credits	5,649,000	12,360,000
Foreign tax credits	583,000	-
Basis differences in fixed assets and other	1,734,000	1,510,000
Basis difference in deferred revenue	-	14,318,000
	37,470,000	132,033,000
Valuation allowance	(37,470,000)	(132,033,000)
Net deferred tax assets	$-	$-

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the application of loss limitation provisions related to ownership changes. The Company assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. The Company also considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax-planning strategies in making this assessment. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period from July 1, 2015 through June 30, 2018. On the basis of these considerations, the Company continued to recognize a full valuation allowance against its net deferred tax assets as of June 30, 2018 and 2017.

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The Company recognizes interest expense and penalties on uncertain income tax positions as a component of interest expense. No interest expense or penalties were recorded for uncertain income tax matters in fiscal 2018, 2017 or 2016. As of June 30, 2018 and 2017, the Company had no liabilities for uncertain income tax matters.

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CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following tables provide quarterly data for the years ended June 30, 2018 and 2017.

	Three Months Ended			
	June 30, 2018	March 31, 2018	December 31, 2017	September 30, 2017
	(amounts in thousands, except per share data)			
Revenues	$20,618	$8,963	$10,612	$26,942
Operating expenses	8,349	9,480	7,671	15,708
Other expense, net	(185)	(241)	(310)	(405)
Income (loss) before income taxes	12,083	(758)	2,631	10,829
Income taxes	(276)	19	399	(225)
Net income (loss)	$11,807	$(739)	$3,030	$10,604
Basic net income (loss) per common share	$0.06	$-	$0.02	$0.05
Diluted net income (loss) per common share	$0.06	$-	$0.01	$0.05
Weighted average number of common shares outstanding used in computing basic net income (loss) per common share	200,581,435	197,485,758	197,238,056	197,112,400
Weighted average number of common shares outstanding used in computing diluted net income (loss) per common share	211,047,927	197,485,758	202,711,616	201,360,736

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	Three Months Ended			
	June 30, 2017	March 31, 2017	December 31, 2016	September 30, 2016
	(amounts in thousands, except per share data)			
Revenues	$33,900	$10,824	$-	$-
Operating expenses	19,581	13,836	9,441	12,435
Other expense, net	(504)	(552)	(588)	(618)
Income (loss) before income taxes	13,815	(3,564)	(10,029)	(13,053)
Income taxes	(500)	-	-	-
Net income (loss)	$13,315	$(3,564)	$(10,029)	$(13,053)
Basic net income (loss) per common share	$0.07	$(0.02)	$(0.06)	$(0.08)
Diluted net income (loss) per common share	$0.07	$(0.02)	$(0.06)	$(0.08)
Weighted average number of common shares outstanding used in computing basic net income (loss) per common share	196,874,145	196,580,519	177,798,511	165,848,269
Weighted average number of common shares outstanding used in computing diluted net income (loss) per common share	197,948,721	196,580,519	177,798,511	165,848,269

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SUBSEQUENT EVENTS

Between July 1, 2018 and September 11, 2018, a total of 1,305,949 shares of the Company’s common stock were sold through Canaccord under the Equity Distribution Agreement for net proceeds of $1,299,263 after payment of commission fees of $40,183.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Our management carried out an evaluation, with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Exchange Act) as of the end of the period covered by this report. Based upon this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2018, our disclosure controls and procedures were effective.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance to management and the board of directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

There was no change in our internal control over financial reporting during the fourth quarter of the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management assessed the effectiveness of our internal control over financial reporting as of June 30, 2018. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework as adopted in 2013. Based on its assessment, management believes that, as of June 30, 2018, our internal control over financial reporting is effective based on those criteria.

Our independent registered accounting firm, KPMG LLP, has audited our internal control over financial reporting as of June 30, 2018. Their report on the effectiveness of our internal control over financial reporting appears below.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Palatin Technologies, Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited Palatin Technologies, Inc. and subsidiary's (the Company) internal control over financial reporting as of June 30, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of June 30, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficiency), and cash flows for each of the years in the three-year period ended June 30, 2018, and the related notes (collectively, the consolidated financial statements), and our report dated September 13, 2018 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding

prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

Philadelphia, Pennsylvania
September 13, 2018

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Identification of Directors

The following table sets forth the names, ages, positions and committee memberships of our current directors. All directors hold office until the next annual meeting of stockholders or until their successors have been elected and qualified. All current directors were elected at our annual stockholders' meeting on June 26, 2018.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	55	Chief Executive Officer, President and a Director
John K.A. Prendergast, Ph.D. (3)	64	Director, Chairman of the Board of Directors
Robert K. deVeer, Jr. (1) (2)	72	Director
J. Stanley Hull (1) (2)	66	Director
Alan W. Dunton, M.D. (1) (2)	64	Director
Angela Rossetti (1) (3)	65	Director
Arlene M. Morris (2) (3)	66	Director
Anthony M. Manning (3)	56	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

CARL SPANA, Ph.D., co-founder of Palatin, has been our Chief Executive Officer and President since June 14, 2000. He has been a director of Palatin since June 1996 and has been a director of our wholly-owned subsidiary, RhoMed Incorporated, since July 1995. From June 1996 through June 14, 2000, Dr. Spana served as an executive vice president and our chief technical officer. From June 1993 to June 1996, Dr. Spana was vice president of Paramount Capital Investments, LLC, a biotechnology and biopharmaceutical merchant banking firm, and of The Castle Group Ltd., a medical venture capital firm. Through his work at Paramount Capital Investments and The Castle Group, Dr. Spana co-founded and acquired several private biotechnology firms. From July 1991 to June 1993, Dr. Spana was a Research Associate at Bristol-Myers Squibb, a publicly-held pharmaceutical company, where he was involved in scientific research in the field of immunology. He was previously a member of the board of the life science company AVAX Technologies, Inc. Dr. Spana received his Ph.D. in molecular biology from The Johns Hopkins University and his B.S. in biochemistry from Rutgers University.

Dr. Spana's qualifications for our board include his leadership experience, business judgment and industry experience. As a senior executive of Palatin for over nineteen years, he provides in-depth knowledge of our company, our drug products under development and the competitive and corporate partnering landscape.

JOHN K.A. PRENDERGAST, Ph.D., co-founder of Palatin, has served as the non-executive Chairman of the board since June 14, 2000, and as a director since August 1996. While Mr. Prendergast has served as a member of the board, he does not, and has not, served in a management or operational role with the company. Dr. Prendergast has been president and sole stockholder of Summercloud Bay, Inc., an independent consulting firm providing services to the biotechnology industry, since 1993. Dr. Prendergast is a director and executive chairman of the board of directors of Antyra, Inc., a privately held biopharmaceutical firm, lead director of Heat Biologics, Inc., a publicly traded clinical stage immunotherapy company, and a director of Recce Pharmaceuticals Ltd., a publicly traded Australian pharmaceutical company developing antibiotic drugs. He was previously a member of the board of the life science companies AVAX Technologies, Inc., Avigen, Inc. and MediciNova, Inc. From October 1991 through December 1997, Dr. Prendergast was a managing director of The Castle Group Ltd., a medical venture capital firm. Dr.

Prendergast received his M.Sc. and Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University.

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Dr. Prendergast brings a historical perspective to our board coupled with extensive industry experience in corporate development and finance in the life sciences field. His prior service on other publicly traded company boards provides experience relevant to good corporate governance practices.

ROBERT K. deVEER, Jr. has been a director of Palatin since November 1998. Since January 1997, Mr. deVeer has been the president of deVeer Capital LLC, a private investment company. He was a director of Solutia Inc., a publicly-held chemical-based materials company, until its merger with Eastman Chemical Company in July 2012. From 1995 until his retirement in 1996, Mr. deVeer served as Managing Director, Head of Industrial Group, at New York-based Lehman Brothers. From 1973 to 1995, he held increasingly responsible positions at New York-based CS First Boston, including Head of Project Finance, Head of Industrials and Head of Natural Resources. He was a managing director, member of the investment banking committee and a trustee of the First Boston Foundation. He received a B.A. in economics from Yale University and an M.B.A. in finance from Stanford Graduate School of Business.

Mr. deVeer has extensive experience in investment banking and corporate finance, including the financing of life sciences companies, and serves as the audit committee's financial expert.

J. STANLEY HULL has been a director of Palatin since September 2005. Mr. Hull has over three decades of experience in the field of sales, marketing and drug development. Mr. Hull joined GlaxoSmithKline, a research-based pharmaceutical company, in October 1987 and retired as Senior Vice President, Pharmaceuticals – North America in May 2010. Mr. Hull was responsible for all commercial activities including sales, marketing, sales training and office operations. Previously Mr. Hull served in the R&D organization of Glaxo Wellcome as Vice President and Worldwide Director of Therapeutic Development and Product Strategy – Neurology and Psychiatry. Prior to his service in the R&D organization he was Vice President of Marketing – Infectious Diseases and Gastroenterology for Glaxo Wellcome-U.S. Mr. Hull started his career in the pharmaceutical industry with SmithKline and French Laboratories in 1978. Mr. Hull received his B.S. in business administration from the University of North Carolina at Greensboro.

Mr. Hull has extensive experience in commercial operations, development and marketing of pharmaceutical drugs and corporate alliances between pharmaceutical companies and biotechnology companies.

ALAN W. DUNTON, M.D., has been a director of Palatin since June 2011. He founded Danerius, LLC, a biotechnology consulting company, in 2006. From November 2015 through March 2018 he was senior vice president of research, development and regulatory affairs for Purdue Pharma L.P., with responsibilities for overall research strategy and development programs. From January 2007 to March 2009, Dr. Dunton served as president and chief executive officer of Panacos Pharmaceuticals Inc. and he served as a managing director of Panacos from March 2009 to January 2011. Dr. Dunton is currently a member of the board of directors of the publicly traded company Oragenics, Inc. He previously served on the board of directors of the publicly traded companies Targacept, Inc., EpiCept Corporation (as Non-Executive Chairman), Adams Respiratory Therapeutics, Inc. (acquired by Reckitt Benckiser Group plc), MediciNova, Inc. and Panacos Pharmaceuticals, Inc. Dr. Dunton has served as a director or executive officer of various pharmaceutical companies, and from 1994 to 2001, Dr. Dunton was a senior executive in various capacities in the Pharmaceuticals Group of Johnson & Johnson, including president and managing director of the Janssen Research Foundation, the primary global R&D organization for Johnson & Johnson. Dr. Dunton received his M.D. degree from New York University School of Medicine, where he completed his residency in internal medicine. He also was a Fellow in Clinical Pharmacology at the New York Hospital/Cornell University Medical Center.

Dr. Dunton has extensive drug development and clinical research experience, having played a key role in the development of more than 20 products to regulatory approval, and also has extensive experience as an executive and officer for both large pharmaceutical companies and smaller biotechnology and biopharmaceutical companies.

ANGELA ROSSETTI has been a director of Palatin since June 2013. From June 2015 through July 2017, she served as Executive Vice President of Cell Machines, Inc., an early stage biopharmaceutical company developing novel protein therapies. Previously, Ms. Rossetti served in pharmaceutical marketing, communications and financial roles, including as Vice President at Pfizer Inc., where she led a global commercial medicine team for smoking cessation, and as an Assistant Vice President at Wyeth, managing a global hemophilia business. Previously, she was President of Ogilvy Healthworld, an advertising business in the pharmaceutical and biotechnology sectors, and served on the Biotech and Pharmaceutical Advisory Board of Danske Capital for six years. Ms. Rossetti graduated from a joint program of the Albert Einstein College of Medicine and Benjamin N. Cardozo School of Law with an M.S.in Bioethics in 2014, has an M.B.A. in Finance from Columbia University Graduate School of Business and a B.A. in Biology from the University of Pennsylvania, and is an adjunct Assistant Professor at New York Medical College.

Ms. Rossetti has extensive experience in worldwide development and marketing of specialty pharmaceuticals, including prefilled syringe products, in communications and development of commercialization plans and in pharmaceutical and biotechnology finance.

ARLENE M. MORRIS has been a director of Palatin since June 2015. Since May 2015 she has served as the chief executive officer of Willow Advisors, LLC. From April 2012 until May 2015 she was President and Chief Executive Officer of Syndax Pharmaceuticals, Inc., a privately held biopharmaceutical company focused on the development and commercialization of an epigenetic therapy for treatment-resistant cancers, and was a member of the board of directors from May 2011 until May 2015. From 2003 to January 2011, Ms. Morris served as the President, Chief Executive Officer and a member of the board of directors of Affymax, Inc., a publicly traded biotechnology company. Ms. Morris has also held various management and executive positions at Clearview Projects, Inc., a corporate advisory firm, Coulter Pharmaceutical, Inc., a publicly traded pharmaceutical company, Scios Inc., a publicly traded biopharmaceutical company, and Johnson & Johnson, a publicly traded healthcare company. She is currently a member of the board of directors of Viveve Medical, Inc., a publicly traded female healthcare medical device company, miRagen Therapeutics, Inc., a publicly traded microRNA therapeutics company, and Neovacs, SA, a French publicly traded biotechnology company, and was a director of Biodel Inc., a publicly traded specialty pharmaceutical company, from 2015 until its merger with Albireo Limited in 2016, and Dimension Therapeutics, Inc., a publicly traded gene therapy company, until its acquisition by Ultragenyx Pharmaceutical Inc. in 2017. Ms. Morris received a B.A. in Biology and Chemistry from Carlow College.

Ms. Morris has extensive experience in the biotechnology industry, including prior leadership positions, current senior management and board service, and experience as chief executive officer of companies with product candidates in phase 3 clinical trials.

ANTHONY M. MANNING, Ph.D., has been a director of Palatin since September 2017. Since 2013, Dr. Manning has been senior vice president of research at Momenta Pharmaceuticals, Inc., a publicly traded biopharmaceutical company developing therapeutics for autoimmune indications as well as biosimilars and generic versions of complex drugs. From 2011 to 2013, he was senior vice president of research and development at Aileron Therapeutics, Inc., a publicly traded biopharmaceutical company developing stapled peptide therapeutics for cancers and other diseases. From 2007 to 2011, he was vice president and head of inflammation and autoimmune diseases research at Biogen, Inc., a publicly traded biopharmaceutical company developing medicines for neurological and neurodegenerative conditions. From 2002 to 2007, he was vice president and global therapy area head for Roche Pharmaceuticals, the pharmaceutical division of Roche Holding AG, and from 2000 to 2002 he was vice president of Pharmacia, a global pharmaceutical company acquired by Pfizer in 2002. Dr. Manning received his Ph.D., M.Sc. and B.Sc. from the University of Otago, Dunedin, New Zealand.

Dr. Manning has extensive experience in translational research and development of new pharmaceutical products, and in pharmaceutical and biotechnology research, development and business strategy.

The Board and Its Committees

Committees and meetings. The board has an audit committee, a compensation committee and a nominating and corporate governance committee. During fiscal 2018, the board met five times, the audit committee met four times, the compensation committee met three times and the nominating and corporate governance committee met two times. Each director attended at least 75% of the total number of meetings of the board and committees of the board on which he served. The independent directors meet in executive sessions at least annually, following the annual board meeting. We do not have a policy requiring our directors to attend stockholder meetings. With the exception of Drs. Prendergast and Spana, the directors did not attend the annual meeting of stockholders held on June 26, 2018.

Audit committee. The audit committee reviews the engagement of the independent registered public accounting firm and reviews the independence of the independent registered public accounting firm. The audit committee also reviews the audit and non-audit fees of the independent registered public accounting firm and the adequacy of our internal control procedures. The audit committee is currently composed of four independent directors, Mr. deVeer (chair), and

Dr. Dunton, Ms. Rossetti and Mr. Hull. The board has determined that the members of the audit committee are independent, as defined in the listing standards of the NYSE American, and satisfy the requirements of the NYSE American as to financial literacy and expertise. The board has determined that at least one member of the committee, Mr. deVeer, is the audit committee financial expert as defined by Item 407 of Regulation S-K. The responsibilities of the audit committee are set forth in a written charter adopted by the board and updated as of October 1, 2013, a copy of which is available on our web site at www.palatin.com.

Compensation committee. The compensation committee reviews and recommends to the board on an annual basis employment agreements and compensation for our officers, directors and some employees, and administers our 2011 Plan and the options still outstanding which were granted under previous stock option plans. The compensation committee is composed of Dr. Dunton (chair), Ms. Morris and Messrs. deVeer and Hull. The board has determined that the members of the compensation committee are independent, as defined in the listing standards of the NYSE American. Our Chief Executive Officer aids the compensation committee by providing annual recommendations regarding the compensation of all executive officers, other than himself. Our Chief Financial Officer supports the committee in its work by gathering, analyzing and presenting data on our compensation arrangements and compensation in the marketplace.

The responsibilities of the compensation committee are set forth in a written charter adopted by the board effective October 1, 2013, a copy of which is available on our web site at www.palatin.com. The committee administers our 2011 Plan, under which it has delegated to an officer its authority to grant stock options to employees and to a single-member committee of the board its authority to grant restricted stock units to officers and to grant options and restricted stock units to our consultants, but in either instance not to grant options or restricted stock units to themselves, any member of the board or officer, or any person subject to Section 16 of the Exchange Act.

Nominating and corporate governance committee. The nominating and corporate governance committee assists the board in recommending nominees for directors, and in determining the composition of committees. It also reviews, assesses and makes recommendations to the board concerning policies and guidelines for corporate governance, including relationships of the board, the stockholders and management in determining our direction and performance. The responsibilities of the nominating and corporate governance committee are set forth in a written charter adopted by the board and updated as of October 1, 2013, a copy of which is available on our web site at www.palatin.com. The nominating and corporate governance committee is composed of Dr. Prendergast (chair), Mss. Rossetti and Morris and Dr. Manning, each of whom meets the independence requirements established by the NYSE American.

Duration of Office. Unless a director resigns, all directors hold office until the next annual meeting of stockholders or until their successors have been elected and qualified. Directors serve as members of committees as the board determines from time to time.

Communicating With Directors

Generally, stockholders or other interested parties who have questions or concerns should contact Stephen T. Wills, Secretary, Palatin Technologies, Inc., 4B Cedar Brook Drive, Cranbury, NJ 08512. However, any stockholder or other interest party who wishes to address questions regarding our business directly to the board of directors, or any individual director, can direct questions to the board members or a director by regular mail to the Secretary at the address above or by e-mail at boardofdirectors@palatin.com. Stockholders or other interested parties may also submit their concerns anonymously or confidentially by postal mail.

Communications are distributed to the board, or to any individual directors as appropriate, depending on the facts and circumstances outlined in the communication, unless the Secretary determines that the communication is unrelated to the duties and responsibilities of the board, such as product inquiries, resumes, advertisements or other promotional material. Communications that are unduly hostile, threatening, illegal or similarly unsuitable will also not be distributed to the board or any director. All communications excluded from distribution will be retained and made available to any non-management director upon request.

Board Role in Risk Oversight

Our board, as part of its overall responsibility to oversee the management of our business, considers risks generally when reviewing our strategic plan, financial results, business development activities, legal and regulatory matters. The board satisfies this responsibility through regular reports directly from our officers responsible for oversight of particular risks. The board's risk management oversight also includes full and open communications with management to review the adequacy and functionality of the risk management processes used by management. The board's role in risk oversight has no effect on the board's leadership structure. In addition, committees of the board assist in its risk oversight responsibility, including:

The audit committee assists the board in its oversight of the integrity of the financial reporting and our compliance with applicable legal and regulatory requirements. It also oversees our internal controls and compliance activities, and meets privately with representatives from our independent registered public accounting firm.

The compensation committee assists the board in its oversight of risk relating to compensation policies and practices. The compensation committee annually reviews our compensation policies, programs and procedures, including the incentives they create and mitigating factors that may reduce the likelihood of excessive risk taking, to determine whether they present a significant risk to our company.

Board Leadership Structure

Since 2000, the roles of chairman of the board and chief executive officer have been held by separate persons. John K.A. Prendergast, Ph.D., a non-employee director, has served as Chairman of the board since June 2000. Carl Spana, Ph.D., has been our Chief Executive Officer and President since June 2000. Generally, the chairman is responsible for advising the chief executive officer, assisting in long-term strategic planning, and presiding over meetings of the board, and the chief executive officer is responsible for leading our day-to-day performance. While we do not have a written policy with respect to separation of the roles of chairman of the board and chief executive officer, the board believes that the existing leadership structure, with the separation of these roles, provides several important advantages, including: enhancing the accountability of the chief executive officer to the board; strengthening the board's independence from management; assisting the board in reaching consensus on particular strategies and policies; and facilitating robust director, board, and executive officer evaluation processes.

Code of Corporate Conduct and Ethics

We have adopted a code of corporate conduct and ethics, updated as of March 11, 2016, that applies to all of our directors, officers and employees, including our Chief Executive Officer and Chief Financial Officer. You can view the code of corporate conduct and ethics at our website, www.palatin.com. We will disclose any amendments to, or waivers from, provisions of the code of corporate conduct and ethics that apply to our directors, principal executive and financial officers in a current report on Form 8-K, unless the rules of the NYSE American permit website posting of any such amendments or waivers.

Executive Officers

Executive officers are appointed by the board and serve at the discretion of the board. Each officer holds his position until his successor is appointed and qualified. The current executive officers hold office under employment agreements.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	55	Chief Executive Officer, President and Director
Stephen T. Wills, MST, CPA	61	Chief Financial Officer, Chief Operating Officer, Executive Vice President, Secretary and Treasurer

Additional information about Dr. Spana is included above under the heading "Identification of Directors."

STEPHEN T. WILLS, CPA, MST, has been Executive Vice President, Secretary, Treasurer and Chief Financial Officer since 1997 and was Executive Vice President of Operations from 2005 until June 2011, when he was appointed Chief Operating Officer and Executive Vice President. Since March 2017, Mr. Wills has served as a director, and since October 2017 as non-executive chairman, of MediWound Ltd., a publicly-traded biopharmaceutical company providing products for severe burns, chronic and other hard-to-heal wounds. Mr. Wills served as executive chairman and interim principal executive officer of Derma Sciences, Inc. ("Derma"), a publicly-held company providing advanced wound care products, from December 2015 until February 2017 when Derma was acquired by Integra LifeSciences Holding Corporation. Mr. Wills also served as the lead director of Derma until December 2015 and as Derma's chief financial officer from 1997 to 2000. Mr. Wills is chairman of the board of trustees of The Hun School of

Princeton, New Jersey. From 1991 to 2000 he was the president and chief operating officer of Golomb, Wills & Company, P.C., a public accounting firm. Mr. Wills, a certified public accountant, received his B.S. in accounting from West Chester University, and an M.S. in taxation from Temple University.

Section 16(A) Beneficial Ownership Reporting Compliance

The rules of the SEC require us to disclose failures to file or late filings of reports of stock ownership and changes in stock ownership required to be filed by our directors, officers and holders of more than 10% of our common stock. To the best of our knowledge, all of the filings for our directors, officers and holders of more than 10% of our common stock were made on a timely basis in fiscal 2018.

Item 11. Executive Compensation.

Fiscal 2018 Summary Compensation Table

The following table summarizes the compensation earned by or paid to our principal executive officer and our principal financial officer, who constitute all of our executive officers, for fiscal 2018 and fiscal 2017. We have no defined benefit or actuarial pension plan, and no deferred compensation plan.

Name and Principal Position	Fiscal Year	Salary ($)	Stock awards (1) ($)	Option awards (1) ($)	Nonequity incentive plan compensation (2)($)	All other compensation (3)($)	Total ($)
Carl Spana, Ph.D., Chief Executive Officer and President	2018	490,700	1,418,500	1,029,882	263,000	13,857	3,215,939
	2017	476,400	368,050	367,368	458,000	13,250	1,683,068
Stephen T. Wills, MST, CPA, Chief Financial Officer, Chief Operating Officer and Executive Vice President	2018	448,300	1,189,125	869,371	240,000	13,827	2,760,623
	2017	435,200	338,330	336,570	438,000	13,250	1,561,350

(1)
Amounts in these columns represent the aggregate grant date fair value for stock awards and option awards computed using either the Black-Scholes model or a multifactor Monte Carlo simulation. For a description of the assumptions we used to calculate these amounts, see Note 14 to the consolidated financial statements included in this Annual Report.

(2)
Bonus amounts.

(3)
Consists of matching contributions to 401(k) plan.

Employment Agreements

Effective July 1, 2016, we entered into employment agreements with Dr. Spana and Mr. Wills which continue through June 30, 2019 unless terminated earlier. Under these agreements, which replaced substantially similar agreements that expired on June 30, 2016, Dr. Spana is serving as Chief Executive Officer and President at a base salary of $476,400 per year and Mr. Wills is serving as Chief Financial Officer and Chief Operating Officer at a base salary of $435,200 per year. Each agreement also provides for:

annual discretionary bonus compensation, in an amount to be decided by the compensation committee and approved by the board, based on achievement of yearly performance objectives; and

participation in all benefit programs that we establish, to the extent the executive’s position, tenure, salary, age, health and other qualifications make him eligible to participate.

Each agreement allows us or the executive to terminate the agreement upon written notice, and contains other provisions for termination by us for “cause,” or by the employee for “good reason” or due to a “change in control” (as these terms are defined in the employment agreements and set forth below). Early termination may, in some circumstances, result in severance pay at the salary then in effect, plus continuation of medical and dental benefits then in effect for a period of two years (Dr. Spana) or 18 months (Mr. Wills). In addition, the agreements provide that options and restricted stock units granted to these officers accelerate upon termination of employment except for voluntary resignation by the officer or termination for cause. In the event of retirement, termination by the officer for good reason, or termination by us other than for “cause”, options may be exercised until the earlier of twenty-four months following termination or expiration of the option term. Arrangements with our named executive officers in connection with a termination following a change in control are described below. Each agreement includes non-competition, non-solicitation and confidentiality covenants.

The annual incentive bonus for the named executive officers is determined based on corporate performance and also individual achievements and performance, as warranted. The target bonus payout for both fiscal 2018 and fiscal 2017 was 50% of base salary. In determining the annual incentive bonus opportunity for executives, the executive's annual base salary is multiplied by the target bonus percentage. The resulting amount is then multiplied by the corporate performance percentage approved by the compensation committee, which is dependent on the achievement of corporate performance goals, and also potentially adjusted upwards or downwards for individual executives based on their individual contribution toward the corporate results during the relevant year. For fiscal 2018, the compensation committee determined that our named executive officers achieved 107% of their target objectives, consisting primarily of progress relating to the Vyleesi program, including filing an NDA and acceptance of the NDA by FDA, and entering into license agreements on Vyleesi with Fosun and Kwangdong and secondarily to advances in MC1r anti-inflammatory programs and other corporate items, and our financial condition. In February 2017 the compensation committee awarded a special, one-time cash bonus of $220,000 to each of the named executive officers based on positive data for Vyleesi in the Phase 3 clinical trials and entering into a North American licensing agreement with AMAG. In June 2017, the compensation committee determined that our named executive officers achieved 100% of their target objectives, after giving consideration to the February 2017 award, based on results of the Vyleesi program, and secondarily to advances in MC14 anti-inflammatory programs and NPR programs.

Stock Option and Restricted Stock Unit Grants

On June 26, 2018, we granted 356,000 restricted stock units to Dr. Spana and 303,000 restricted stock units to Mr. Wills, which vest as to 50% of the number of shares granted on each anniversary of the grant date. We also granted 533,000 stock options to Dr. Spana and 454,000 stock options to Mr. Wills, which vest as to 25% of the number of shares granted on each anniversary of the grant date. These options have an exercise price of $1.00, the fair market value of the common stock on the date of grant, and they expire on June 26, 2028.

In the fall of 2017, the compensation committee retained Korn Ferry Hay Group ("Hay Group"), a nationally-recognized global human resources consulting firm, as its independent compensation advisor. Hay Group principally provided analysis, advice and recommendations regarding named executive officer and non-employee director compensation. Hay Group developed a peer group of twenty-one similarly-situated public companies which was used as the basis for competitive market analysis both for beneficial ownership and target total cash compensation. It was determined that long term incentive equity grant value for the named executive officers was below the peer group twenty-fifth percentile, and significantly below the peer group median. It was determined by the compensation committee to make a special grant to the named executive officers to position each executive around peer group median levels, and to promote performance and retention.

On December 12, 2017, the board ratified the compensation committee determination that additional equity grants were necessary in order to reward, motivate and retain the non-employee directors, based in part on the report of the Hay Group, which reviewed non-employee director compensation in peer companies, and determined that equity compensation below median for the peer group, and we granted the Chairman of the board 60,000 restricted stock units and an option to purchase 60,000 shares of common stock, and the other serving non-employee directors, other than Dr. Manning, received 30,000 restricted stock units and an option to purchase 30,000 shares of common stock, with Dr. Manning receiving 15,000 restricted stock units and an option to purchase 15, 000 shares of common stock. The restricted stock units vest as to one-third of the total award on the first, second and third anniversary of the grant date, conditioned on continued service as a director through the applicable vesting dates. All of the options have an exercise price of $0.85 per share, the closing price of our common stock on the date of grant, vest as to one-third of the total award on the first, second and third anniversary of the grant date, expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

On June 20, 2017 we granted 595,000 restricted stock units to Dr. Spana and 545,000 restricted stock units to Mr. Wills, which vest as to 50% on each anniversary of the grant date. We also granted 938,000 stock options to Dr. Spana and 859,000 stock options to Mr. Wills, which vest as to 25% on each anniversary of the grant date. These options have an exercise price of $0.37, the fair market value of the common stock on the date of grant, and they expire on June 20, 2027.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table summarizes all of the outstanding equity-based awards granted to our named executive officers as of June 30, 2018, the end of our fiscal year.

	Option awards (1)						Stock awards (2)			
Name	Option or stock award grant date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan award: number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($) (3)	Equity incentive plan awards: number of unearned shares, unit or other rights that have not vested (#)	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested ($)
Carl Spana	07/01/08	25,000	-		1.80	07/01/18				
	07/01/09	25,000	-		2.80	07/01/19				
	06/22/11	300,000	-		1.00	06/22/21				
	07/17/12	150,000	-		0.72	07/17/22				
	06/27/13	275,000	-		0.62	06/27/23				
	06/25/14	175,000	-		1.02	06/25/24				
	06/11/15	225,000	75,000		1.08	06/11/25				
	09/07/16	199,500	232,500		0.68	09/07/26				
	06/20/17	234,500	703,500		0.37	06/20/27				

	12/12/17	-	625,000		0.85	12/12/27				
	12/12/17	187,500		437,500	0.85	12/12/27				
	6/26/18	-	533,000		1.00	6/26/28				
	12/08/15						81,250	78,813		
	09/07/16						107,500	104,275		
	06/20/17						297,500	288,575		
	12/12/17						625,000	606,250	437,500	424,375
	6/26/18						356,000	345,320		
Total Stock Awards							1,467,250	$1,423,233	437,500	$424,375
Stephen T. Wills	07/01/08	20,000	-		1.80	07/01/18				
	07/01/09	20,000	-		2.80	07/01/19				
	06/22/11	250,000	-		1.00	06/22/21				
	07/17/12	135,000	-		0.72	07/17/22				
	06/27/13	250,000	-		0.62	06/27/23				
	06/25/14	150,000	-		1.02	06/25/24				
	06/11/15	202,500	67,500		1.08	06/11/25				
	09/07/16	182,250	213,750		0.68	09/07/26				
	06/20/17	214,750	644,250		0.37	06/20/27				
	12/12/17	-	575,000		0.85	12/12/27				
	12/12/17	135,000		332,500	0.85	12/12/27				
	6/26/18	-	454,000		1.00	6/26/28				
	12/08/15						75,000	72,750		
	09/07/16						100,000	97,000		
	06/20/17						272,500	264,325		
	12/12/17						575,000	557,750	332,500	322,525
	6/26/18						303,000	293,910		
Total Stock Awards							1,325,500	$1,285,735	332,500	$322,525

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(1)
Stock option vesting schedules: all options granted on or before June 10, 2015 have fully vested. Options granted after June 10, 2015 vest over four years with 1/4 of the shares vesting per year starting on the first anniversary of the grant date, provided that the named executive officer remains an employee. See “Termination and Change-In-Control Arrangements” below, except for performance-based options granted on December 12, 2017, which vest according to the terms of the grant described above.

(2)
Time-based stock award vesting schedule: stock awards consist of restricted stock units granted December 8, 2015, as to 162,500 shares for Dr. Spana and 150,000 shares for Mr. Wills, which vest in equal amounts over a four year period, provided that the named executive officer remains an employee; restricted stock units granted on September 7, 2016, as to 182,500 shares for Dr. Spana and 168,000 shares for Mr. Wills, which have fully vested as of September 7, 2018; restricted stock units granted on June 20, 2017, as to 595,000 shares for Dr. Spana and 545,000 shares for Mr. Wills, which vest in equal amounts over a two year period, provided that the named executive officer remains an employee; restricted stock units granted on December 12, 2017, as to 575,000 shares for Dr. Spana and 625,000 shares for Mr. Wills, which vest in equal amounts over a four year period, provided that the named executive officer remains an employee; and restricted stock units granted on June 26, 2018, as to 356,000 shares for Dr. Spana and 303,000 shares for Mr. Wills, which vest in equal amounts over a two year period, provided that the named executive officer remains an employee. Both time-based and performance-based restricted stock unit awards contain deferred delivery provisions provision for delivery of the common stock after the grantee’s separation from service or a defined changed in control. See “Stock Options and Restricted Stock Unit Awards” above and “Termination and Change-In-Control Arrangements” below.

(3)
Calculated by multiplying the number of restricted stock units by $0.97, the closing market price of our common stock on June 29, 2018, the last trading day of our most recently completed fiscal year.

Termination and Change-In-Control Arrangements

The employment agreements, stock option agreements and restricted stock unit agreements with Dr. Spana and Mr. Wills contain the following provisions concerning severance compensation and the vesting of stock options and restricted stock units upon termination of employment or upon a change in control. The executive’s entitlement to severance, payment of health benefits and accelerated vesting of options is contingent on the executive executing a general release of claims against us.

Termination Without Severance Compensation. Regardless of whether there has been a change in control, if we terminate employment for cause or the executive terminates employment without good reason (as those terms are defined in the employment agreement and set forth below), then the executive will receive only his accrued salary and vacation benefits through the date of termination. He may also elect to receive medical and dental benefits pursuant to COBRA for up to two years (Dr. Spana) or 18 months (Mr. Wills), but must remit the cost of coverage to us. Under the terms of our outstanding options and restricted stock units, all unvested options and restricted stock units would terminate immediately, and vested options would be exercisable for three months after termination.

Severance Compensation After Death or Disability. In the event of the executive’s death or disability, we will provide lump sum severance pay equal to 24 months (for Dr. Spana) or 18 months (for Mr. Wills) of base pay, as well as the opportunity for COBRA benefits as described above under “Termination Without Severance Compensation.”

Severance Compensation Without a Change in Control. If we terminate or fail to extend the employment agreement without cause, or the executive terminates employment with good reason, then the executive will receive as severance

pay his salary then in effect, paid in a lump sum, plus medical and dental benefits at our expense, for a period of two years (Dr. Spana) or 18 months (Mr. Wills) after the termination date. In addition, upon such event all unvested options would immediately vest and be exercisable for two years after the termination date or, if earlier, the expiration of the option term, and all unvested restricted stock units would accelerate and become fully vested.

Severance Compensation After a Change in Control. If, within one year after a change in control, we terminate employment or the executive terminates employment with good reason, then the executive will receive as severance pay 200% (Dr. Spana) or 150% (Mr. Wills) of his salary then in effect, paid in a lump sum, plus medical and dental benefits at our expense, for a period of two years (Dr. Spana) or 18 months (Mr. Wills) after the termination date. We would also reimburse the executive for up to $25,000 in fees and expenses during the six months following termination, for locating employment. We would also reimburse the executive for any excise tax he might incur on “excess parachute payments” (as defined in Section 280G(b) of the Internal Revenue Code). All unvested options would immediately vest and be exercisable for two years after the termination date or, if earlier, the expiration of the option term. All unvested restricted stock units would vest upon a change in control, without regard to whether the executive’s employment is terminated.

Option and Restricted Stock Unit Vesting Upon a Change in Control. Options and restricted stock units granted under the 2011 Stock Incentive Plan vest upon a change in control. If any options granted under the 2005 Stock Plan are to be terminated in connection with a change in control, those options will vest in full immediately before the change in control.

Definitions. Under the employment agreements, a “change in control,” “cause” and “good reason” are defined as follows:

A “change in control” occurs when:

(a)
any person or entity acquires more than 50% of the voting power of our outstanding securities;

(b)
the individuals who, during any twelve-month period, constitute our board of directors cease to constitute at least a majority of the board of directors;

(c)
the consummation of a merger or consolidation; or

(d)
we sell substantially all our assets.

The term “cause” means:

(a)
the occurrence of (i) the executive’s material breach of, or habitual neglect or failure to perform the material duties which he is required to perform under, the terms of his employment agreement; (ii) the executive’s material failure to follow the reasonable directives or policies established by or at the direction of our board of directors; or (iii) the executive’s engaging in conduct that is materially detrimental to our interests such that we sustain a material loss or injury as a result thereof, provided that the breach or failure of performance is not cured, to the extent cure is possible, within ten days of the delivery to the executive of written notice thereof;

(b)
the willful breach by the executive of his obligations to us with respect to confidentiality, invention and non-disclosure, non-competition or non-solicitation; or

(c)
the conviction of the executive of, or the entry of a pleading of guilty or nolo contendere by the executive to, any crime involving moral turpitude or any felony.

The term “good reason” means the occurrence of any of the following, with our failure to cure such circumstances within 30 days of the delivery to us of written notice by the executive of such circumstances:

(a)
any material adverse change in the executive’s duties, authority or responsibilities, which causes the executive’s position with us to become of significantly less responsibility, or assignment of duties and responsibilities inconsistent with the executive’s position;

(b)

a material reduction in the executive's salary;

(c)
our failure to continue in effect any material compensation or benefit plan in which the executive participates, unless an equitable arrangement has been made with respect to such plan, or our failure to continue the executive's participation therein (or in a substitute or alternative plan) on a basis not materially less favorable, both in terms of the amount of benefits provided and the level of the executive's participation relative to other participants;

(d)
our failure to continue to provide the executive with benefits substantially similar to those enjoyed by the executive under any of our health and welfare insurance, retirement and other fringe-benefit plans, the taking of any action by us which would directly or indirectly materially reduce any of such benefits, or our failure to provide the executive with the number of paid vacation days to which he is entitled; or

(e)
the relocation of the executive to a location which is a material distance from Cranbury, New Jersey.

Director Compensation

The following table sets forth the compensation we paid to all directors during fiscal 2018, except for Dr. Spana, whose compensation is set forth above in the Summary Compensation Table and related disclosure. Dr. Spana did not receive any separate compensation for his services as a director.

Name	Fees earned or paid in cash ($)	Stock awards ($) (1) (2)	Option awards ($) (1) (2)	Total ($)
John K.A. Prendergast, Ph.D.	97,500	107,000	68,552	273,052
Robert K. deVeer, Jr.	62,500	53,500	34,275	150,275
J. Stanley Hull	55,000	53,500	34,275	142,775
Alan W. Dunton, M.D.	62,500	53,500	34,275	150,275
Angela Rossetti	52,500	53,500	34,275	140,275
Arlene Morris	52,500	53,500	34,275	140,275
Anthony Manning, Ph.D.	30,885	67,750	44,043	142,678

(1)
The aggregate number of shares underlying option awards and stock awards outstanding at June 30, 2018 for each director was:

	Option awards	Stock awards
Dr. Prendergast	604,750	226,000
Mr. deVeer	332,500	108,000
Mr. Hull	329,000	108,000
Dr. Dunton	262,000	98,000
Ms. Rossetti	214,500	88,000
Ms. Morris	169,500	78,000
Dr. Manning	97,000	97,000

(2)
Amounts in these columns represent the aggregate grant date fair value for stock awards and option awards. For a description of the assumptions we used to calculate these amounts, see Note 14 to the consolidated financial statements included in this Annual Report. Amounts in this column include options granted on June 26, 2018 for our current fiscal year ending June 30, 2019.

Non-Employee Directors' Equity Grants. Our non-employee directors receive an annual equity grant at the board meeting closest to the beginning of each fiscal year, or such other date as may be determined by the board.

On June 20, 2018, the Chairman of the board received 56,000 restricted stock units which vest on June 26, 2019, and an option to purchase 56,000 shares of common stock, and each other serving non-employee director received 28,000 restricted stock units which vest on June 26, 2019, and an option to purchase 28,000 shares of common stock. All of the options have an exercise price of $1.00 per share, the closing price of our common stock on the date of grant, vest in twelve monthly installments beginning on July 31, 2018, expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

On December 12, 2017, the board ratified the compensation committee determination that additional equity grants were necessary in order to reward, motivate and retain the non-employee directors, based in part on the report of the Hay Group, which reviewed non-employee director compensation in peer companies, and determined that equity compensation below median for the peer group, and we granted the Chairman of the board 60,000 restricted stock units and an option to purchase 60,000 shares of common stock, and the other serving non-employee directors, other than Dr. Manning, received 30,000 restricted stock units and an option to purchase 30,000 shares of common stock, with Dr. Manning receiving 15,000 restricted stock units and an option to purchase 15, 000 shares of common stock. The restricted stock units vest as to one-third the total award on the first, second and third anniversary of the grant date, conditioned on continued service as a director through the applicable vesting dates. All of the options have an exercise price of $0.85 per share, the closing price of our common stock on the date of grant, vest as to one-third of the total award on the first, second and third anniversary of the grant date, expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

On June 20, 2017, the Chairman of the board received 108,000 restricted stock units which vested on June 20, 2018, and an option to purchase 108,000 shares of common stock, and each other serving non-employee director received 54,000 restricted stock units which vested on June 20, 2018, and an option to purchase 54,000 shares of common stock. All of the options have an exercise price of $0.37 per share, the closing price of our common stock on the date of grant, vest in twelve monthly installments beginning on July 31, 2017, expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

Non-Employee Directors' Cash Compensation. Dr. Prendergast serves as Chairman of the board and for fiscal 2018 received an annual retainer of $87,500, payable quarterly. Other non-employee directors received an annual base retainer of $40,000, payable on a quarterly basis. The chairperson of the audit committee received an additional annual retainer of $12,500, the chairperson of the compensation committee received an additional annual retainer of $12,500 and the chairperson of the corporate governance committee received an additional annual retainer of $7,500. Members of the foregoing committees, other than the non-employee Chairman, received an additional retainer of one-half the retainer payable to the committee chairperson. For the fiscal year ending June 30, 2019, Dr. Prendergast serves as Chairman of the board and will received an annual retainer of $90,000, payable quarterly. Other non-employee directors will receive an annual base retainer of $45,000, payable on a quarterly basis. The chairperson of the audit committee will receive an additional annual retainer of $15,000, the chairperson of the compensation committee will receive an additional annual retainer of $15,000 and the chairperson of the corporate governance committee will receive an additional annual retainer of $10,000. Members of the foregoing committees, other than the non-employee Chairman, receive an additional retainer of one-half the retainer payable to the committee chairperson.

Non-Employee Directors' Expenses. Non-employee directors are reimbursed for expenses incurred in performing their duties as directors, including attending all meetings of the board and any committees on which they serve.

Employee Directors. Employee directors are not separately compensated for services as directors, but are reimbursed for expenses incurred in performing their duties as directors, including attending all meetings of the board and any committees on which they serve.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance Under Equity Compensation Plans. The table below provides information on our equity compensation plans as of June 30, 2018:

Equity Compensation Plan Information
as of June 30, 2018

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)

Equity compensation plans approved by security holders	22,099,338(1)	$0.76(2)	7,559,248
Equity compensation plans not approved by security holders	25,000(3)	$0.70	-
Total	22,124,338		7,559,248

(1)
Includes 12,526,312 options and 9,323,876 restricted stock units granted under our 2011 Stock Incentive Plan and 249,150 options granted under our 2005 Stock Plan. Our 2005 Stock Plan has terminated, but termination does not affect awards that are currently outstanding under this plan. The shares subject to outstanding awards under the 2005 Stock Plan, if forfeited prior to exercise, will become available for issuance under the 2011 Stock Incentive Plan.

(2)
The amount in column (a) for equity compensation plans approved by security holders includes 9,323,876 shares reserved for issuance on vesting of outstanding restricted stock units, granted under our 2011 Stock Incentive Plan, which vest on various dates through June 26, 2022, subject to the fulfillment of service, market conditions, or performance conditions. Because no exercise price is required for issuance of shares on vesting of the restricted stock units, the weighted-average exercise price in column (b) does not take the restricted stock units into account.

(3)
Consists of two warrants to purchase 12,500 shares at $0.70 per share issued in connection with a contract for financial advisory services.

Beneficial Ownership Tables. The tables below show the beneficial stock ownership and voting power, as of September 11, 2018, of:

each director, each of the named executive officers, and all current directors and officers as a group; and

all persons who, to our knowledge, beneficially own more than five percent of the common stock or Series A preferred stock.

“Beneficial ownership” here means direct or indirect voting or investment power over outstanding stock and stock which a person has the right to acquire now or within 60 days after September 13, 2018. See the footnotes for more detailed explanations of the holdings. Except as noted, to our knowledge, the persons named in the tables beneficially own and have sole voting and investment power over all shares listed.

The common stock has one vote per share and the Series A preferred stock has approximately 15 votes per share of Series A preferred stock. Voting power is calculated on the basis of the aggregate of common stock and Series A preferred stock outstanding as of September 12, 2018, on which date 202,048,804 shares of common stock and 4,030 shares of Series A preferred stock, convertible into 61,145 shares of common stock, were outstanding.

The address for all members of our management and directors is c/o Palatin Technologies, Inc., 4B Cedar Brook Drive, Cranbury, NJ 08512. Addresses of other beneficial owners are in the table.

MANAGEMENT:

Class	Name of beneficial owner	Amount and nature of beneficial ownership	Percent of class	Percent of total voting power
Common	Carl Spana, Ph.D.	3,934,352(1)	1.9%	*
Common	Stephen T. Wills	3,535,739(2)	1.7%	*
Common	John K.A. Prendergast, Ph.D.	829,683(3)	*	*
Common	Robert K. deVeer, Jr.	473,392(4)	*	*
Common	J. Stanley Hull	444,332(5)	*	*
Common	Alan W. Dunton, M.D.	387,352(6)	*	*
Common	Angela Rossetti	322,332(7)	*	*
Common	Arlene M. Morris	252,332(8)	*	*

Common	Anthony M. Manning, Ph.D.	36,332(9)	*	*
	All current directors and executive officers as a group (nine persons)	10,215,846(10)	4.9%	1.2%

*Less than one percent.

(1)
Includes 1,849,000 shares of common stock underlying outstanding options and 1,343,750 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(2)
Includes 1,610,750 shares of common stock underlying outstanding options and 1,200,500 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(3)
Includes 474,750 shares of common stock underlying outstanding options and 100,000 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(4)
Includes 264,916 shares of common stock underlying outstanding options and 50,000 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(5)
Includes 261,332 shares of common stock underlying outstanding options and 50,000 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(6)
Includes 213,332 shares of common stock underlying outstanding options and 40,000 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(7)
Includes 165,832 shares of common stock underlying outstanding options and 30,000 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(8)
Consists of 120,832 shares of common stock underlying outstanding options and 20,000 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee’s separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(9)
Consists of 22,832 shares of common stock underlying outstanding options and 13,500 shares of common stock underlying restricted stock units, all of which shares of common stock underlying restricted stock units have vested but not been delivered under deferred delivery provisions provision for delivery after the grantee's separation from service or a defined changed in control, but does not include shares of common stock underlying outstanding options or restricted stock unit awards that have not vested and will not vest within 60 days.

(10)
Includes 7,831,326 shares of common stock underlying outstanding options and restricted stock units.

MORE THAN 5% BENEFICIAL OWNERS:

Class	Name and address of beneficial owner	Amount and nature of beneficial ownership (1)	Percent of class Percent of total voting power
Series A Preferred	Steven N. Ostrovsky 43 Nikki Ct. Morganville, NJ 07751	500	12.4%*
Series A Preferred	Thomas L. Cassidy IRA Rollover 38 Canaan Close		