SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 10-K

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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, 2020

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

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

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

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

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 every Interactive Data File required to be submitted 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). Yes ☑ No ☐

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.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2019): $176,555,811

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (September 24, 2020): 229,855,417

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" means 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:

- our business, financial condition, and results of operations may be adversely affected by global health epidemics, including the novel strain of coronavirus ("COVID-19") pandemic, such as, for example, increase in costs of and delays in conducting human clinical trials and the performance of our contractors and suppliers, and reduction in our productivity or the productivity of our contractors and suppliers;
- our ability to successfully commercialize Vyleesi® (the trade name for bremelanotide) for the treatment of premenopausal women with hypoactive sexual desire disorder ("HSDD") in the United States, which may be adversely affected by delays or disruptions related to the ongoing COVID-19 pandemic;
- our ability to develop the infrastructure to successfully manufacture, through contract manufacturers, Vyleesi, and to successfully market and distribute Vyleesi in the United States;
- our ability to meet post-marketing requirements of the U.S. Food and Drug Administration ("FDA") to conduct two additional studies and one additional clinical trial for Vyleesi;
- our expectations regarding the potential market size and market acceptance for Vyleesi for HSDD in the United States and elsewhere in the world;
- our expectations regarding performance of our exclusive licensees of Vyleesi for the treatment of premenopausal women with HSDD, which is a type of female sexual dysfunction ("FSD"), including:
  - ❑ 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
  - ❑ Kwangdong Pharmaceutical Co., Ltd. ("Kwangdong") for the Republic of Korea ("Korea");
- our expectations and the ability of our licensees to timely obtain approvals and successfully commercialize Vyleesi in countries other than the United States;
- estimates of our expenses, future revenue and capital requirements;
- our ability to achieve profitability;
- our ability to obtain additional financing on terms acceptable to us, or at all, including unavailability of funds or delays in receiving funds as a result of the ongoing COVID-19 pandemic;
- 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;
- and our other product candidates, if approved for commercial use;
- our expectations regarding the clinical efficacy and utility of our melanocortin agonist product candidates for treatment of inflammatory and autoimmune related diseases and disorders, including ocular indications;
- our ability to compete with other products and technologies treating the same or similar indications as 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, including delays and additional costs related to the ongoing COVID-19 pandemic;
- 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.

PART I

Item 1. Business.

Our Business Overview

Palatin 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.

In January 2020, our North American licensee for Vyleesi® (bremelanotide injection), AMAG Pharmaceuticals, Inc. ("AMAG"), announced that it had completed a strategic review of its product portfolio and business strategy, and was pursuing options to divest its female health products, including Vyleesi. On July 27, 2020, Palatin and AMAG announced that they had mutually terminated the license agreement for Vyleesi effective July 24, 2020, and that Palatin was assuming responsibility for manufacturing, marketing and distribution of Vyleesi in the United States.

Melanocortin Receptor System. The melanocortin receptor ("MCr") system is hormone driven, with effects on food intake, metabolism, sexual function, inflammation and immune system responses. 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 lead product, Vyleesi, was approved by the FDA on June 21, 2019, and since July 24, 2020 we have been marketing Vyleesi in the United States. Prior to July 24, 2020, the product was marketed in North America by AMAG pursuant to a license agreement which was terminated on that date. Vyleesi, a melanocortin receptor agonist, is an "as needed" therapy used in anticipation of sexual activity and self-administered by premenopausal women with HSDD in the thigh or abdomen via a single-use subcutaneous auto-injector. The most common adverse events are nausea, flushing, injection site reactions, headache and vomiting. Vyleesi is contraindicated in women with uncontrolled hypertension or known cardiovascular disease. In addition, the Vyleesi label includes precautions that it may cause (i) small, transient increases in blood pressure with a corresponding decrease in heart rate; (ii) focal hyperpigmentation (darkening of the skin on certain parts of the body), including the face, gums (gingiva) and breasts; and (iii) nausea.

Our current new product development activities focus primarily on peptides which are agonists at MC1r, and in some instances additional melanocortin receptors, with potential to treat inflammatory and autoimmune diseases such as dry eye disease, which is also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. We believe that 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 peptide and small molecule agonists with potential utility in obesity and metabolic-related disorders, including rare disease and orphan indications.

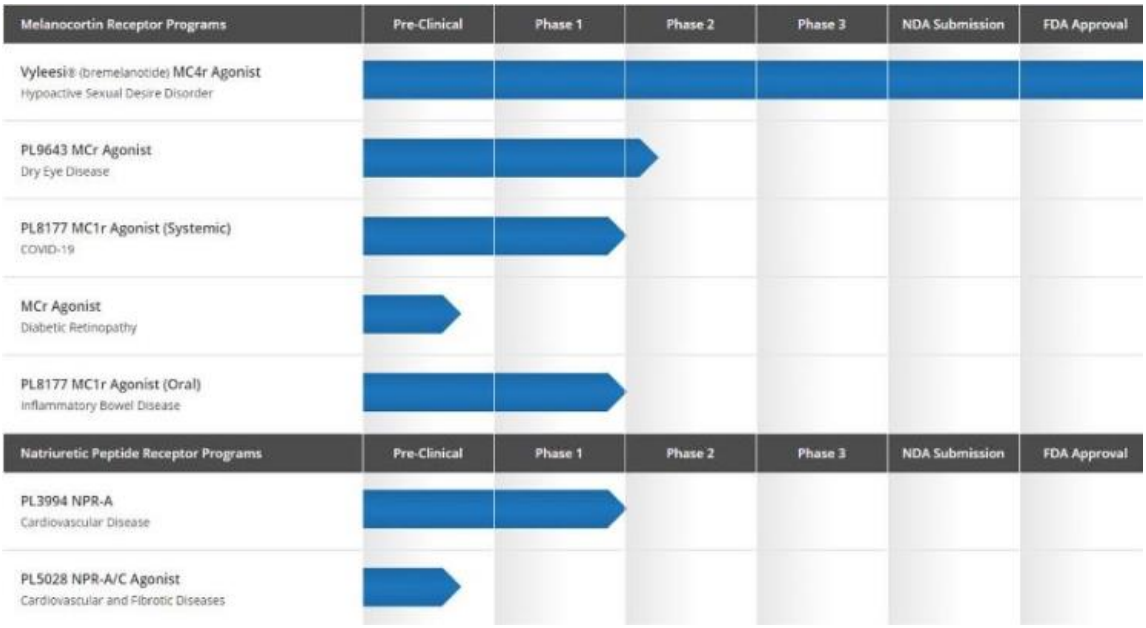
Natriuretic Peptide Receptor System. The natriuretic peptide receptor ("NPR") system regulates cardiovascular functions, and therapeutic agents modulating this system have potential to treat fibrotic diseases, cardiovascular diseases, including reducing cardiac hypertrophy and fibrosis, heart failure, acute asthma, pulmonary diseases and hypertension. We have designed and are developing potential NPR candidate drugs 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").

Our Business Strategy. Key elements of our business strategy include:

- Maximizing revenue from Vyleesi by marketing Vyleesi in the United States, supporting our existing licensees for China and South Korea, and licensing Vyleesi for the United States and additional regions;
- Assembling and maintaining a team to create, develop and commercialize MCr and NPR products addressing unmet medical needs;
- 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.

Pipeline Overview

The following chart illustrates the status of our drug development programs and Vyleesi, which has been approved by the FDA for the treatment of premenopausal women with acquired, generalized HSDD.



Melanocortin Receptor Programs

Vyleesi for HSDD. Vyleesi, the registered trademark for bremelanotide injection, was approved by the FDA on June 21, 2019 for the treatment of premenopausal women with acquired, generalized HSDD. AMAG, which had exclusively licensed Vyleesi for North America, initiated sales and marketing efforts for Vyleesi in the United States in August 2019, with a national launch in September 2019. In January 2020, AMAG announced that, based on a review of their business strategy, including an adverse outcome of an FDA advisory panel review of their lead health product Makena® (hydroxyprogesterone caproate injection), they made a decision to divest Vyleesi and another female healthcare product. In July 2020, Palatin and AMAG entered into a termination agreement, pursuant to which the license agreement was terminated, Palatin regained all North America rights for Vyleesi, and AMAG made a $12.0 million payment to Palatin at closing and will make a $4.3 million payment to Palatin by March 31, 2021. Palatin has assumed Vyleesi manufacturing agreements, and AMAG has transferred information, data and assets related exclusively to Vyleesi, including existing inventory. AMAG is providing certain transition services to Palatin for a period to ensure continued patient access to Vyleesi during the transition period. Palatin will reimburse AMAG for the agreed upon costs of the transition services.

Vyleesi faces competition primarily from Addyi® (flibanserin), which was introduced into the market in October 2015 for the treatment of HSDD in pre-menopausal women and is marketed by Sprout Pharmaceuticals, Inc. We are not aware of any company actively developing another melanocortin receptor agonist drug for the treatment of HSDD. However, we are aware of several other drugs at various stages of development, most of which are being developed for the treatment of HSDD that are to be taken on a chronic, typically once-daily, basis. There may be other companies developing new drugs for FSD indications other than HSDD, which may compete with Vyleesi, some of which may be in clinical trials in the U.S. or elsewhere. Vyleesi may also compete with products prescribed “off-label” by healthcare providers.

Vyleesi is distributed nationally through specialty pharmacies. Our marketing strategy focuses on efforts to establish Vyleesi as the preferred option for women and healthcare providers seeking a treatment for HSDD, which we implement through media such as direct-to-consumer marketing in search and social media channels. We also focus our Vyleesi marketing efforts towards healthcare professionals, who play a significant role in increasing HSDD and Vyleesi awareness among their patients. As the potential of Vyleesi is demonstrated, Palatin will explore licensing marketing and distribution rights for the United States to a marketing partner.

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. Upon the license agreement becoming effective on February 2, 2017, AMAG paid us $60.0 million as a one-time initial payment, and has reimbursed us $25.0 million for direct out-of-pocket expenses incurred in development and regulatory activities necessary to file an NDA, less certain expenses directly paid by AMAG. Upon the FDA acceptance of the Vyleesi NDA filing for HSDD, AMAG paid us a $20.0 million milestone payment less agreed deductions for expenses incurred by AMAG, and upon FDA approval of Vyleesi, AMAG paid us a $60.0 million milestone payment.

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 we 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 $0.5 million, less required tax withholding. Upon the first commercial sale of Vyleesi in Korea we will receive a $3.0 million milestone payment and 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 HSDD and all other indications outside Korea and China. We are actively seeking potential partners for marketing and commercialization rights for Vyleesi for HSDD outside the licensed territories, including entering into a license agreement for marketing and commercialization rights for Vyleesi in the United States. However, we may not be able to enter into suitable agreements with potential partners on acceptable terms, if at all.

Our Current Product Development Strategy. We are designing and developing potent and highly selective MC1r agonist peptides and agonist peptides specific for more than one melanocortin receptor for treatment of a variety of inflammatory and autoimmune indications. In animal models our peptides agonists, 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 immune cells, such as monocytes and T cells, to reduce immune response, 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 multiple MCr peptide drug candidates for selected inflammatory disease and autoimmune indications. MC1r plays a role in many 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 our drug candidates will be able to successfully treat diseases in human patients.

PL9643 for Dry Eye Disease and Anti-Inflammatory Ocular Indications. PL9643, a peptide melanocortin agonist active at multiple MCrs, including MC1r and MC5r, is our lead clinical development candidate for anti-inflammatory ocular indications, including dry eye disease, which is also known as keratoconjunctivitis sicca. Dry eye disease is a syndrome with symptoms including irritation, redness, discharge and blurred vision. It may result from an autoimmune disease such Sjögren's syndrome, an ocular lipid or mucin deficiency, blink disorders, abnormal corneal sensitivity or environmental factors. It is estimated to affect over 30 million people in the United States.

We have developed an aqueous eye drop formulation which will be used in clinical trials in a single use delivery device. We held a pre-Investigational New Drug ("IND") meeting with the FDA on Phase 2 study design and the overall development program through Phase 3 registration studies, submitted the IND to the FDA, and initiated the Phase 2 clinical trial in February 2020. The Phase 2 study is a multi-center, randomized double-masked and placebo-controlled study evaluating the efficacy and safety of PL9643 ophthalmic solution (topical eye drops) compared to placebo for the treatment of the signs and symptoms of dry eye. The study completed enrollment in July 2020, with 160 participants enrolled at three sites in the US. Patients were randomized in a 1:1 ratio into two arms, PL9643 or placebo, and undergo twelve weeks of treatment. The two primary endpoints are inferior corneal fluorescein staining and ocular discomfort, and data is expected as early as the fourth quarter of calendar year 2020. If results from the Phase 2 study support advancing to Phase 3, we will initiate a Phase 3 efficacy study as early as mid-2021.

Systemic PL8177 for COVID-19 Related Indications. We are developing PL8177 as a potential treatment for patients with COVID-19, the disease caused by infection with the SARS-CoV-2 virus, and having hypoxemic respiratory failure with or without acute respiratory distress syndrome. This decision was based on positive results in preclinical multiple inflammatory disease models and a lung injury model, which showed the ability of PL8177 to reduce inflammation, protect lung tissue and reduce lung fibrosis. We are conducting additional preclinical studies to support the filing of an IND with the FDA for this indication, and thereafter initiate a Phase 2 study. We are seeking support for the proposed Phase 2 study from the federal government and other sources, and if external support is not available we may determine not to initiate Phase 2 studies.

Oral PL8177 for Inflammatory Bowel Diseases. PL8177, a selective MC1r agonist peptide, is our lead clinical development candidate for inflammatory bowel diseases, including ulcerative colitis. PL8177 is a cyclic peptide comprised of seven amino acids. We filed an IND application on PL8177 in late 2017 and in 2018 successfully completed subcutaneous dosing of human subjects in a Phase 1 single and multiple ascending dose clinical safety study.

For ulcerative colitis and other inflammatory bowel diseases we will administer PL8177 in an oral formulation designed to deliver PL8177 to the interior wall of the diseased bowel. PL8177 activates MC1r present on the interior wall of the bowel in ulcerative colitis and other inflammatory bowel diseases. We believe that delivering PL8177 directly to MC1r in the bowel wall will maximize treatment effect while minimizing any systemic or off-target effects.

A Phase 2 study in ulcerative colitis using the oral, delayed-release, polymer formulation of PL8177 is scheduled to start in the first half of calendar year 2021, and may take up to one year to complete.

Systemic PL8177 for Non-Infectious Uveitis. PL8177 has been granted orphan drug designation by the FDA for the treatment of non-infectious intermediate, posterior, pan and chronic anterior uveitis. Non-infectious uveitis is a group of inflammatory diseases that produces swelling and destroys eye tissue and can result in vision loss. A Phase 2 program in non-infectious uveitis using a systemic delivery formulation of PL8177 is under development.

Melanocortin Peptides for Diabetic Retinopathy. We are conducting preclinical studies with melanocortin peptides in diabetic retinopathy models and are scheduled to complete these studies by the first half of calendar year 2021. If results support advancing the program, we would conduct required safety studies and manufacture drug product under Good Manufacturing Practices ("GMP") regulations preparatory to filing an IND and initiating clinical studies.

Natriuretic Peptide Receptor Programs

Natriuretic Peptide Receptor Systems. The NPR system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of cardiovascular and fibrotic diseases. 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 made potential NPR candidate drugs that are selective for one or more different natriuretic peptide receptors, including NPR-A, NPR-B, and NPR-C.

PL3994 for Mechanism of Action Studies. PL3994 is an NPR-A agonist and synthetic mimetic of the endogenous neuropeptide hormone atrial natriuretic peptide ("ANP"). PL3994 activates NPR-A, a receptor known to play a role in cardiovascular homeostasis. Consistent with being an NPR-A agonist, PL3994 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. PL3994 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.

In conjunction with clinicians at a major research institution, PL3994 is entering Phase 2A clinical trial supported by a grant from the American Heart Association in the fourth quarter of calendar year 2020. We have conducted Phase 1 safety studies with PL3994, with no serious or severe adverse events. Consistent with the PL3994 mechanism of action, elevations in plasma cGMP levels, increased diuresis and increased natriuresis were all observed for several hours after single subcutaneous doses.

Because of the limited patent term remaining on PL3994, we do not intend to pursue PL3994 as a pharmaceutical product but are utilizing it to establish the mechanism of action and pharmaceutical utility of synthetic mimetics of ANP.

PL5028 for Cardiovascular and Fibrotic Disease. PL5028, a dual NPR-A and NPR-C agonist we developed, is in preclinical development for cardiovascular and fibrotic diseases, including reducing cardiac hypertrophy and fibrosis. We have ongoing academic collaborations with several institutions with PL5028.

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 PL3994, 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 *M*etal *I*on-induced *D*istinctive *A*rray of *S*tructures. 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.

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. Other companies may also introduce products using new technologies that may be competitive with our proposed products. 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, approved products such as Vyleesi may 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 other than Vyleesi 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. The Boxed Warning was modified by FDA in April 2019 to clarify that there remains a concern about consuming alcohol close in time to taking flibanserin, but that alcohol does not have to be avoided completely. Specifically, the Boxed Warning reflects women should discontinue drinking alcohol at least two hours before taking flibanserin at bedtime, or to skip the flibanserin dose that evening. 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.

Melanocortin Receptor 1 Agonist Drug Products for Inflammatory and Autoimmune Diseases. Many inflammatory disease-related indications are treated using systemic steroids or immunosuppressant drugs, all of which have side effects that can be dose limiting. There are a number of approved biological drugs and other biological drugs under development for treatment of inflammatory disease-related indications, which typically affect only one pathway in the inflammatory response. Many of these drugs address symptoms, but do not resolve the underlying inflammatory or autoimmune disease process.

Oral PL8177 for Inflammatory Bowel Diseases/Ulcerative Colitis. FDA-approved drugs used in treatment of ulcerative colitis include aminosalicylates such as mesalazine and related drugs, immunosuppressive drugs such as cyclosporine and azathioprine, corticosteroids such as prednisone and other steroids, and various biologic drugs, including tumor necrosis factor inhibitors such as infliximab and adalimumab. There are a number of drugs in development for ulcerative colitis, including Janus kinase inhibitors, monoclonal antibodies specific for one or more immune system cytokine signaling molecules, and additional classes of immunomodulatory drugs. There are no reported MC1r agonist drugs in clinical trials for inflammatory bowel diseases, including ulcerative colitis. If one or more of the competing products under development are approved and can effectively treat ulcerative colitis with an acceptable side effect profile, such products could reduce the market for oral PL8177 for inflammatory bowel diseases, including ulcerative colitis.

Systemic PL8177 for Non-Infectious Uveitis. FDA-approved drugs used in treatment of non-infectious uveitis include immunosuppressive medications such as adalimumab, sold under the brand name Humira® and other brand names, and corticosteroids such as prednisone and other steroids. There are other products in development, including tumor necrosis factor inhibitors and interleukin receptor agonists such as gevokizumab, as well as formulations of glucocorticoid receptor agonists. There are no reported MC1r agonist drugs in clinical trials for non-infectious uveitis. If one or more the competing product candidates under development is approved and can resolve non-infectious uveitis with an acceptable side effect profile, it could reduce the market for systemic PL8177 for this indication.

Systemic PL8177 for Treatment of Patients with COVID-19. On a global level there are numerous vaccines, anti-viral drugs for treating COVID-19 and drugs for treating symptoms of COVID-19 in development, and there is a concerted effort by the federal government to develop effective therapies. There is also intense pressure for federal funding, through a number of programs, for developing effective therapies. If one or more competing product candidates under development is approved and can resolve COVID-19 and effectively treat symptoms and sequela of COVID-19, it could reduce the market for systemic PL8177 for treatment of patients with COVID-19.

PL9643 for Anti-Inflammatory Ocular Indications. PL9643 is under development for dry eye diseases and may also have utility for other inflammatory ocular indications. 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 over 20 agents reported to be in or have completed Phase 2 development. Products under development include tumor necrosis factor agonists, alpha-2 adrenergic receptor agonist, calcineurin inhibitors and nicotinic receptor agonists, among others. 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 PL9643 for dry eye disease.

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 have completed Phase 3 clinical trials with an MC4r agonist peptide drug for rare genetic disorders of obesity.

PL5028 for Cardiovascular and Fibrotic Indications. We are evaluating potential clinical indications for PL5028, and have not determined a specific indication for initial studies. There are many approved drugs and drugs in clinical studies for cardiovascular diseases, including drugs that directly modulate the NPR system, such as nesiritide (sold under the trade name Natrecor®), a recombinant NPR-B peptide drug, and a combination drug comprised of sacubitril and valsartan (sold under the trade name Entresto®), which inhibits both the angiotensin II receptor and neprilysin, which is an enzyme that inactivates endogenous active natriuretic peptides. This combination drug results in increases of endogenous active ANP levels. In addition, there are a number of approved drugs and drugs in development for treatment of cardiovascular and fibrotic diseases through mechanisms or pathways other than agonism of NPR-A.

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 three 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, South Africa, the Republic of Georgia, Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Japan, Mexico, New Zealand, Netherlands, Norway, Philippines, Poland, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom and related patent applications pending in Brazil, Canada, China, Hong Kong, India, Indonesia, Korea, Malaysia, and Vietnam. 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. 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 own two issued United States patents claiming the Vyleesi drug substance. The issued United States patents have a term until 2020, and applications have been filed to extend the term of one patent for a maximum period of 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. An interim extension for a period of one year from the original expiration date of both patents of June 28, 2020, was granted in May 2020, but the length of the final extension which may be granted under the Hatch-Waxman Amendments has not been determined. 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 patents 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. The presumptive term of the issued patents 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 three issued patents in the United States and issued patents in Australia, Canada, 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, 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 five issued patents in the United States, and issued patents in Australia, Belgium, Canada, China, France, Germany, Ireland, Israel, Japan, Korea, Mexico, New Zealand, Russia, South Africa, Sweden, Switzerland and the United Kingdom 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, and India. 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 PL3994 substance and other natriuretic peptide receptor agonist compounds that we have developed and an issued United States patent claiming a precursor molecule to the PL3994 substance, both of which expire in 2027. Corresponding patents on the PL3994 substance and other natriuretic peptide receptor agonist compounds were issued in a number of countries throughout the world, but we do not intend to develop a PL3994 product for commercialization and will cease maintaining patents outside the United States. We also own an issued United States patent claiming use of the PL3994 substance for treatment of acute asthma and chronic obstructive pulmonary disease, which expires in 2031. 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 our other product candidates, 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 with 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 ministries of health and other authorities in foreign governments. 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;
- clinical studies to evaluate safety and efficacy;
- 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 new drug products or 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 FDA's Center for Drug Evaluation and Research ("CDER"). For combination products, 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 development is typically conducted in three sequential phases, Phases 1, 2, and 3, involving clinical trials with increasing numbers 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 data demonstrating the effectiveness and safety 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 commitments 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's current 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

Vyleesi and any other 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, licensees or 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, the 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, the 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 the 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 the 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 FFDCA, 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. Vyleesi is classified as a Tier 3 drug by at least two insurers, and will likely be classified as a Tier 3 drug by additional insurers. Thus reimbursement will be limited for Vyleesi for treatment of premenopausal women with HSDD. Flibanserin, sold under the trade name Addyi, is similarly classified as a Tier 3 drug. 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 other reimbursement systems.

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.

Vyleesi is manufactured using contract manufacturing companies. Pursuant to the termination of the license agreement with AMAG, we have assumed contracts relating to manufacturing, and intend to manufacture Vyleesi for sales in the United States and to our licensees throughout the world.

Our PL3994 product candidate is a peptide mimetic molecule, incorporating a proprietary amino acid mimetic structure and amino acids. We have had a contract manufacturer make the active pharmaceutical ingredient in quantities sufficient for Phase 1 and Phase 2.

Our MC1r and MCr agonist product candidates are synthetic peptides. We have had a contract manufacturer make both the PL8177 and PL9643 peptides in suitable scale for toxicity studies and under GMP for clinical trial use. The PL8177 drug product for uveitis has been manufactured for clinical trial use, and manufacturing process development is ongoing for an oral formulation of PL8177 preparatory to manufacturing oral PL8177 drug product for clinical trial use. While the production process for making peptide active pharmaceutical ingredient 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. Manufacturing drug product, such as the oral formulation of PL8177, similarly may involve production, formulation and other problems not present in manufacturing at laboratory scale.

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 product liability and commercialization risks and certain clinical trial risks.

Employees

As of September 24, 2020, we employed 20 people full time, of whom 14 are engaged in research and development activities and five 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.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC (*www.sec.gov*).

Item 1A. Risk Factors.

Risks Related to Our Financial Results and Need for Financing

We have a history of substantial net losses, including a net loss of $22.4 million for the year ended June 30, 2020, and while we had net income for the years ended June 30, 2019 and 2018, we expect to incur substantial net losses over the next few years, and we may never achieve or maintain profitability.

As of June 30, 2020, we had an accumulated deficit of $318.2 million. We had a net loss of $22.4 million for the year ended June 30, 2020, compared to $35.8 million of net income for the year ended June 30, 2019, and $24.7 million of net income for the year ended June 30, 2018. We may not sustain profitability in future years, depending on numerous factors, including profitability of Vyleesi, whether and when development and sales milestones are met, whether and when we enter into license agreements for any of our products under development, 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 MC1r, MCr and natriuretic peptide receptor 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.

Until we commenced selling Vyleesi in July 2020 upon termination of our license agreement with AMAG, 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. Because of termination of the license agreement with AMAG relating to Vyleesi, we cannot accurately forecast sales of Vyleesi. However, we anticipate a net loss from Vyleesi sales for at least the year ending June 30, 2021. For the foreseeable future, we will have to fund our operations and capital expenditures from license, royalty and contract revenue under license agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all. We will not have product revenue from our products in development unless and until we receive approval from the FDA or other equivalent regulatory authorities outside the United States, and to date the only approved product is Vyleesi in the United States. 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 MC1r product candidates and secondarily on our natriuretic peptide product candidates. As of June 30, 2020, we had cash and cash equivalents of $82.9 million, with current liabilities of $3.9 million. We believe we have sufficient existing capital resources to fund our planned operations through at least September 2021. We will need additional funding to complete development activities and required clinical trials for our MC1r product candidates and, if those clinical trials are successful (which we cannot predict), to complete submission of required regulatory applications to the FDA.

We cannot predict product sales for Vyleesi for HSDD in the United States, so we may not have 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 develop and maintain manufacturing, marketing and distribution capability for sales of Vyleesi in the United States, including our ability to enter into agreements with one or more third parties to conduct activities relating to the commercialization of Vyleesi;
- our ability to enter into one or more licensing or similar agreements for Vyleesi outside of Korea and China;
- the timing of obtaining regulatory approvals for Vyleesi for HSDD in markets outside the United States;
- the expense and timing of obtaining regulatory approvals for 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, filed an NDA on Vyleesi for HSDD with the FDA, and received approval on Vyleesi from 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;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates;

- the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with the FDA's current 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 commercial success of Vyleesi for HSDD, but we and our licensees may never successfully commercialize Vyleesi for HSDD or obtain approvals in countries other than the United States.

To date, we have invested most of our efforts and financial resources in the research and development of Vyleesi for HSDD, which was approved by the FDA in June 2019. Since July 24, 2020, the effective date of the termination of our license agreement with AMAG for Vyleesi, we have been responsible for manufacturing, marketing and distribution of Vyleesi in the United States. We licensed all rights to commercialize Vyleesi in China to Fosun and in Korea to Kwangdong. We have not yet received regulatory approval to commercialize Vyleesi in China or Korea, and regulatory approval in these countries cannot be assured.

Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful commercialization of Vyleesi for HSDD, as well as any future product candidates. The clinical and commercial success of Vyleesi and 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 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 and future product candidates;
- our ability to successful manufacture Vyleesi for worldwide markets;
- our success and the success of our licensees in educating physicians and patients about the benefits, administration and use of Vyleesi for HSDD;
- 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, 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 any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current GMP;
- our ability to successfully commercialize Vyleesi for HSDD in the United States;
- 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 direct sales of Vyleesi for HSDD in the United States and the license agreements with 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.

Production and supply of Vyleesi depend on contract manufacturers over whom we do not have any control, and there may not be 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. We have contracts with third parties to make the Vyleesi combination product. The 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 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 or negatively impact our ability to market Vyleesi. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process. If we are not able to obtain adequate supplies of Vyleesi, it will be difficult for us to market and commercialize Vyleesi and compete effectively.

The effect of COVID-19 and other possible pandemics and outbreaks could result in material adverse effects on our clinical trials, business, financial condition and results of operations.

We have active and planned clinical trial sites in the United States and planned clinical trial sites in Europe, and our licensees have planned clinical trial sites in Asia-Pacific countries. As the COVID-19 pandemic continues to spread around the globe, we will likely experience disruptions that could severely impact our planned clinical trials, including potential Phase 3 clinical trials with PL9643 in the United States for dry eye disease, a planned Phase 2 clinical trial with PL8177 for ulcerative colitis, a planned Phase 2 clinical trial with PL3994, an NPR-A agonist, in heart failure patients in collaboration with two major academic medical centers, and clinical trials planned to be conducted in the People's Republic of China and the Republic of Korea by our licensees for Vyleesi, Fosun and Kwangdong.

It is possible that the COVID-19 pandemic may delay enrollment in our clinical trials due to prioritization of medical and hospital resources toward the outbreak, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results.

The spread of COVID-19 may also result in the inability of our suppliers to deliver clinical drug supplies on a timely basis or at all. In addition, medical centers and hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials.

The COVID-19 pandemic and measures to prevent the spread of COVID-19 subject us to various risks and uncertainties that could materially adversely affect our clinical trials, business, financial condition and results of operation, including the following:

- our ability to recruit subjects for clinical trials and studies for our product candidates and to timely complete clinical trials and other studies;
- our ability to successfully market Vyleesi, given significant limitations in person-to-person marketing and contacts, including limitations in educating physicians and other health care professionals about the benefits, administration and use of Vyleesi for HSDD;
- adverse impacts on our ability to manufacture and distribute Vyleesi, including due to the negative impact of COVID-19 on air travel, as well as temporary disruptions, restrictions or closures of facilities of our suppliers and contract manufacturers in the Vyleesi manufacturing chain;
- adverse impacts of COVID-19 on our ability to successful manufacture product candidates for clinical trials and to successfully manufacture Vyleesi for the United States market and clinical trials elsewhere in the world;
- adverse impacts on our operations resulting from remote working arrangements;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families, delays or difficulties in conducting site visits and other required travel, and the desire of employees to avoid contact with large groups of people;
- the inability of global suppliers of raw materials or components used in the manufacture of our products, or contract manufacturers of our products, to supply and/or transport those raw materials, components and products to us in a timely and cost effective manner due to shutdowns, interruptions or delays, limiting and precluding the production of our finished products, impacting our ability to supply customers, reducing our sales, increasing our costs of goods sold, and reducing our absorption of overhead;

- the illiquidity or insolvency of our suppliers, vendors and customers, or their inability to pay our invoices in full or in a timely manner, due to the reduction in their revenues caused by the cancellation or delay of procedures and other factors, which could potentially reduce our cash flow and our liquidity;
- delays in our ability, and the ability of our development partners, to conduct, enroll and complete clinical development programs;
- the instability to worldwide economies, financial markets, social institutions, labor markets and the healthcare systems as a result of the COVID-19 pandemic, which could result in an economic downturn that could adversely impact our business, results of operations and financial condition, as well as that of our investors, suppliers, customers or other business partners;
- changes in customer behavior and preferences for Vyleesi, as customers may experience financial difficulties or may delay or reduce their spending in light of COVID-19; and
- a recurrence of the COVID-19 pandemic after social distancing and other similar measures have been relaxed.

Most of our employees have transitioned to remote working arrangements, and we have not determined how long these arrangements will last. While remote working has not had a significant adverse impact on our financial results or our operations to date, there can be no assurance that these arrangements will not ultimately result in lower work efficiency and productivity, which in turn may adversely affect our business. Certain employees, such as laboratory personnel, cannot work remotely, and COVID-19 may adversely affect our ability to conduct research and preclinical studies, and undertake other activities related to development of potential products. In addition, COVID-19 has resulted in industry events and business travel being suspended, cancelled or significantly curtailed, which may negatively impact our ability to identify and form relationships with potential development and marketing partners.

The extent to which the global COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain or treat its impact, among others. The COVID-19 pandemic has adversely affected economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding, if needed.

Our product candidates other than Vyleesi, including PL9643 for dry eye disease and PL8177 for the treatment of COVID-19, 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, including PL9643 for dry eye disease and PL8177 for the treatment of COVID-19, 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;
- for injectable products, inability to develop or obtain a supplier for a suitable 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 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.

In light of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. If we were to develop a treatment for COVID-19, the economic value of such a therapeutic treatment to us could be limited.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our COVID-19 therapeutic treatment, if any.

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, HMOs and government programs such as Medicare and Medicaid; and
- advantages over alternative treatment methods.

There is one other 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. While we believe that an on-demand drug for HSDD has competitive advantages compared to chronic or daily use 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 flibanserin and 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 Vyleesi or any of 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, or if the incidence of side effects increase or other problems are observed with Vyleesi, 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 marketplace 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.

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 reported as being developed for HSDD and other FSD indications, including 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 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 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 marketed products and products reported to be in late stage clinical trials. Similarly, the inflammatory bowel disease and ulcerative colitis markets are highly competitive, with a number of marketed products and products reported to be in late stage clinical trials.

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.

In general, the biopharmaceutical industry is highly competitive. We are likely to encounter significant competition with respect to Vyleesi, MC1r product candidates, MCr 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, MCr 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. 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 PL8177, PL9643, PL3994 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 Vyleesi and 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 are currently working to establish sales and marketing capabilities for Vyleesi in the United States, including through establishing agreements with third parties to market and sell Vyleesi. We may not be able to enter into suitable agreements on acceptable terms, if at all, with third parties to market and sell Vyleesi. Engaging a third party to perform these services could impede sales of Vyleesi. If we are unable to establish adequate sales, marketing and distribution capabilities for Vyleesi, whether independently or with third parties, we may not be able to generate sufficient product revenue to support Vyleesi-associated costs and expenses, and our business would suffer. In addition, if we enter into arrangements with third parties to perform sales, marketing and distribution services, we will be dependent on the performance of third parties over whom we have limited control.

If any of our products candidates are approved by the FDA or other regulatory authorities, we must enter into agreements with third parties to market these product candidates or 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 need to hire additional employees in order to commercialize Vyleesi and our product candidates in the future. Any inability to manage future growth could harm our ability to commercialize Vyleesi and ultimately our product candidates, increase our costs and adversely impact our ability to compete effectively.

In order to commercialize Vyleesi and ultimately 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 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, including Vyleesi and 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. We believe that Vyleesi for HSDD will be classified as a Tier 3 drug, as was flibanserin, so that reimbursement will be limited for Vyleesi for treatment of premenopausal women with HSDD. 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. 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 the volume and 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 product liability and commercialization risks and certain clinical trial risks. We, or any corporate collaborators, may not in the future be able to obtain insurance at a reasonable cost or in sufficient amounts, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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;
- HIPAA, 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, PL8177, PL9643, PL3994 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.

Existing coverage for Vyleesi for the treatment of HSDD is classified as a Tier 3 drug by third-party payers, so that demand for Vyleesi 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.

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.

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 may be used in combination with a drug delivery device, such as an injector or other delivery system. Vyleesi is considered a drug-device combination product because of its injection delivery device. 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.

The FDA has required that two postmarketing studies and a clinical trial be conducted on Vyleesi.

In its approval of Vyleesi, under the FFDCA the FDA imposed certain postmarketing requirements, consisting of two studies, one a prospective, registry-base, observational cohort study that compares obstetrical, maternal, fetal/neonatal, and infant outcomes in women exposed to Vyleesi during pregnancy to an internal, unexposed cohort of pregnant women, and the other a retrospective cohort study using electronic claims data that compares maternal, fetal/neonatal, and infant outcomes in women exposed to Vyleesi during pregnancy to an internal, unexposed cohort of pregnant women, and one clinical trial in lactating women who have received Vyleesi to assess potential adverse effects in the breastfed infant and measure bremelanotide concentrations in breast milk using a validated assay. We are evaluating requirements, timelines and costs for these studies and the clinical trial. We do not know the outcomes of the studies or the clinical trials, and do not know whether the outcomes would adversely affect approvals of Vyleesi.

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 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 significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. 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, 2020, the price of our stock has been volatile, ranging from a high of $1.21 per share to a low of $0.36 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 on the effectiveness of our 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 us, 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 24, 2020. 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 24, 2020, 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, 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 24, 2020, there were 44,970,962 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 and delivery of restricted stock units.

As of September 24, 2020, holders of our outstanding dilutive securities had the right to acquire the following amounts of underlying common stock:

- 66,059 shares issuable on the conversion of our immediately convertible Series A Convertible Preferred Stock, subject to adjustment, for no further consideration;
- 20,042,950 shares issuable upon the exercise of stock options at a weighted-average exercise price of $0.79 per share;
- 5,778,105 shares issuable under restricted stock units which vest on dates between December 12, 2020 and June 16, 2024, subject to the fulfillment of service or performance conditions;
- 6,444,353 shares of common stock which have vested under restricted stock unit agreements, but are subject to provisions to delay delivery; and
- 12,639,495 shares issuable upon the exercise of warrants at a weighted-average exercise price of $0.74 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 2025. We also lease approximately 1,700 square feet of laboratory space in the Township of South Brunswick, NJ, and have signed an amendment to expand the lease to approximately 3,600 square feet of laboratory space in the fourth quarter of calendar year 2020 and extend the lease until October 2023. 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.

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 23, 2020 we had approximately 106 record holders of common stock and the closing sales price of our common stock as reported on the NYSE American was $0.49 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 $111,043,160.

Issuer purchases of equity securities. In certain instances we provide our employees with the option to withhold shares to satisfy tax withholding amounts due from the employees upon the vesting of restricted stock units and stock options in connection with our 2011 Stock Incentive Plan. The following 6,696 shares were withheld during the quarter ended June 30, 2020 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 and options:

Fiscal Month Period	Total Number of Shares Purchased [1]	Weighted Average Price 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, 2020 through April 30, 2020	6,696	$ 0.44	-	-
May 1, 2020 through May 31, 2020	-	-	-	-
June 1, 2020 through June 30, 2020	-	-	-	-
Total	6,696	$ 0.44	-	-

(1) Consists solely of 6,696 shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock units and options.

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 23, 2020, 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 immediately prior to Part I, under the heading "Forward-Looking Statements." Forward-looking statements are subject to risk 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, 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 are the most critical.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASC Topic 606"), which, along with amendments from 2015 and 2016 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. ASC Topic 606 replaced most existing revenue recognition guidance in U.S. GAAP when it became effective.

On July 1, 2018, we adopted ASC Topic 606 using the modified retrospective approach, a practical expedient permitted under ASC Topic 606, and applied this approach only to contracts that were not completed as of July 1, 2018. We calculated a one-time cumulative transition adjustment of $500,000, which was recorded on July 1, 2018 to the opening balance of accumulated deficit related to our license agreement with Kwangdong (the "Kwangdong License Agreement") because we determined a significant revenue reversal would not occur in a future period. The one-time adjustment consisted of the recognition of $500,000 of deferred revenue.

Revenue Recognition for Periods Prior to July 1, 2018

We have generated revenue solely through license and collaboration agreements. Prior to July 1, 2018, we recognized revenue in accordance with FASB Accounting Standards Codification ("ASC") Topic 605-25, *Revenue Recognition for Arrangements with Multiple Elements* , which addressed the determination of whether an arrangement involving multiple deliverables contained more than one unit of accounting. A delivered item within an arrangement was considered a separate unit of accounting only if both of the following criteria were met:

- the delivered item had value to the customer on a stand-alone basis; and
- if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered item was considered probable and substantially in control of the vendor.

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

We determined that it was appropriate to recognize such revenue specifically related to the up-front payment the Company received 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 of the accompanying consolidated financial statements for additional information.

Under the license agreement with Fosun for exclusive rights to commercialize Vyleesi in the China (the "Fosun License Agreement"), as discussed in Note 5 of the accompanying consolidated financial statements, we 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 the fiscal year ended June 30, 2018 ("fiscal 2018"), which was the quarter in which the license was granted, since the license had stand-alone value and the upfront payment we received was non-refundable.

Under the Kwangdong License Agreement, as discussed in Note 6 of the accompanying consolidated financial statements, we received consideration in the form of an upfront license fee payment in fiscal 2018 and determined that it was appropriate to record such consideration as deferred revenue because the upfront payment we received is subject to certain refund provisions.

Revenue resulting from the achievement of development milestones was recorded in accordance with the accounting guidance for the milestone method of revenue recognition. Amounts received prior to satisfying the revenue recognition criteria were recorded as deferred revenue on our consolidated balance sheet.

Revenue Recognition for Periods Commencing July 1, 2018

For licenses of intellectual property, we assess, at contract inception, whether the intellectual property is distinct from other performance obligations identified in the arrangement. If the licensing of intellectual property is determined to be distinct, revenue is recognized for nonrefundable, upfront license fees when the license is transferred to the customer and the customer can use and benefit from the license. If the licensing of intellectual property is determined not to be distinct, then the license will be bundled with other promises in the arrangement into one performance obligation. We need to determine if the bundled performance obligation is satisfied over time or at a point in time. If we conclude that the nonrefundable, upfront license fees will be recognized over time, we will need to assess the appropriate method of measuring proportional performance.

Regulatory milestone payments are excluded from the transaction price due to the inability to estimate the probability of reversal. Revenue relating to achievement of these milestones is recognized in the period in which the milestone is achieved.

Sales-based royalty and milestone payments resulting from customer contracts solely or predominately for the license of intellectual property will only be recognized upon occurrence of the underlying sale or achievement of the sales milestone in the future and such sales-based royalties and milestone payments will be recognized in the same period earned.

We recognize revenue for reimbursements of research and development costs under collaboration agreements as the services are performed. We record these reimbursements as revenue and not as a reduction of research and development expenses as we are the principal in the research and development activities based upon our control of such activities, which is considered part of our ordinary activities.

Development milestone payments are generally due 30 business days after the milestone is achieved. Sales milestone payments are generally due 45 business days after the calendar year in which the sales milestone is achieved. Royalty payments are generally due on a quarterly basis 20 business days after being invoiced.

Accrued Expenses

Third parties perform a significant portion of the Company's development activities. The Company reviews the activities performed under all contracts each quarter and accrues expenses and the amount of any reimbursement to be received from its 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 the Company does not identify services performed for it but not billed by the service-provider, or if it underestimates or overestimates the value of services performed as of a given date, reported expenses will be understated or overstated.

Stock-Based Compensation

We expense the fair value of stock options and other equity awards granted. Compensation costs for stock-based awards with time-based vesting are determined using the quoted market price of our common stock on the date of grant or for stock options, the value determined utilizing the Black-Scholes option pricing model, and are recognized 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 our common stock on the date of grant or for stock options, the value is determined utilizing the Black Scholes option pricing model, and are recognized based on the probability of achievement of the performance condition over the service period. The Black-Scholes option pricing model requires us to make estimates of expected volatility and interest rates, which we estimate based on prior experience and public sources of information. The expected term of the option used is based upon the simplified method, which represents the average of the vesting and contractual term. Compensation expense is not adjusted for subsequent changes in the estimates used to calculate fair value or for actual experience. Forfeitures are recognized as they occur. As the amount and timing of compensation expense to be recorded in future periods may be affected by the achievement of performance conditions and employee terminations, stock-based compensation may vary significantly 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, 2020 Compared to the Year Ended June 30, 2019:

Revenue – For the fiscal year ended June 30, 2020 ("fiscal 2020"), we recognized $117,989 in revenue pursuant to our license agreement with AMAG compared to $60,300,476 in revenue for the fiscal year ended June 30, 2019 ("fiscal 2019").

On January 8, 2017, we entered into the AMAG License Agreement 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 by AMAG for direct out-of-pocket expenses we incurred following the effective date of the AMAG 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. We recognized $117,989 and $300,476 for fiscal 2020 and fiscal 2019, respectively, as license and contract revenue which included additional billings for AMAG-related Vyleesi costs.

In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, we were eligible to receive up to $80,000,000 from AMAG in specified regulatory milestone payments upon achievement of certain regulatory milestones. On June 21, 2019, the FDA granted approval of Vyleesi for use in the United States, which triggered a $60,000,000 milestone payment to Palatin. As a result, we recognized $60,000,000 in revenue related to regulatory milestones in fiscal 2019.

Due to the early commercial stage of Vyleesi and the sales and marketing strategy of AMAG, including no charge for the first Vyleesi prescription, AMAG has not generated positive net sales through June 30, 2020, which resulted in no royalties to Palatin during this period. On January 9, 2020, AMAG announced plans to divest Vyleesi.

On July 27, 2020, Palatin and AMAG announced that they had mutually terminated the license agreement for Vyleesi effective July 24, 2020. Under the terms of the termination agreement, the Company regained all North American development and commercialization rights for Vyleesi. AMAG made a $12.0 million payment to the Company at closing and will make a $4.3 million payment to the Company on March 31, 2021. The Company assumed all Vyleesi manufacturing agreements, and AMAG will transfer information, data, and assets related exclusively to Vyleesi, including, but not limited to, existing inventory. AMAG is providing certain transitional services to the Company for a period of time to ensure continued patient access to Vyleesi during the transition back to the Company. The Company will reimburse AMAG for the costs of the transition services.

Research and Development – Total research and development expenses, including general research and development spending, were $13,959,379 for fiscal 2020 compared to $14,857,059 for fiscal 2019. The decrease is a result of lower compensation cost in fiscal 2020 along with lower spending on our Vyleesi program offset by an increase in spending on our other melanocortin receptor programs.

Research and development expenses related to our Vyleesi, PL3994, PL8177, MC1r, MC4r and other preclinical projects were $10,187,786 and $10,129,640 in fiscal 2020 and fiscal 2019, respectively. The increase in spending for fiscal 2020 as compared to fiscal 2019 is a result of increased spending primarily on our melanocortin receptor programs offset by a decrease in spending on our Vyleesi program. 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, PL8177 and PL3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which was $3,771,611 and $4,727,455 in fiscal 2020 and fiscal 2019, respectively. The decrease in general research and development spending is primarily attributable to lower compensation cost in fiscal 2020.

Cumulative spending from inception to June 30, 2020 was approximately $311,400,000 on our Vyleesi program and approximately $154,700,000 on all our other programs (which include PL8177, PL9643, other melanocortin receptor agonists, NPR 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 $9,765,372 for fiscal 2020 compared to $9,699,061 for fiscal 2019. The increase in general and administrative expenses is primarily attributable the final payment made in connection with the Greenhill agreement and professional fees related to the Vyleesi divestiture offset by a decrease in compensation costs.

Other Income (Expense) – Total other income (expense), net was $1,180,757 and $28,707 for fiscal 2020 and fiscal 2019, respectively. For fiscal 2020, we recognized $1,200,898 of investment income offset by $20,141 of interest expense. For fiscal 2019, we recognized $446,268 of investment income offset by $417,561 of interest expense primarily related to our venture debt. The increase in investment income is a result of Company's increased cash position. The decrease in interest expense relates to our paying down of the venture debt.

Income Taxes – For fiscal 2020 and fiscal 2019, the Company recorded no income tax benefit or expense as a result of the generation of and utilization of net operating losses that were subject to a full valuation allowance.

Year Ended June 30, 2019 Compared to the Year Ended June 30, 2018:

Revenue – For fiscal 2019, we recognized $60,300,476 in revenue pursuant to our license agreement with AMAG compared to $67,134,758 in revenue for fiscal 2018 pursuant to our license agreements with AMAG and Fosun.

On January 8, 2017, we entered into the AMAG License Agreement 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 by AMAG for direct out-of-pocket expenses we incurred following the effective date of the AMAG 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. We recognized $300,476 and $42,134,758 for fiscal 2019 and fiscal 2018, respectively, as license and contract revenue which included additional billings for AMAG-related Vyleesi costs of $300,476 and $1,151,243 in fiscal 2019 and fiscal 2018, respectively.

In addition, pursuant to the terms of and subject to the conditions in the AMAG License Agreement, we were eligible to receive up to $80,000,000 from AMAG in specified regulatory milestone payments upon achievement of certain regulatory milestones. On June 4, 2018, the FDA accepted the Vyleesi NDA for filing, which triggered a $20,000,000 milestone payment to Palatin from AMAG, that was recognized in revenue in fiscal 2018. On June 21, 2019, the FDA granted approval of Vyleesi for use in the United States, which triggered a $60,000,000 milestone payment to Palatin. As a result, we recognized $60,000,000 in revenue related to regulatory milestones in fiscal 2019.

On September 6, 2017, we entered into the Fosun License Agreement, which provided for $5,000,000 as a one-time non-refundable upfront payment, which was recorded as revenue during the year ended June 30, 2018. Pursuant to the Fosun License Agreement, $500,000 was withheld in accordance with tax withholding requirements in the Chinese Territories and was recorded as an expense during the year ended June 30, 2018.

Research and Development – Total research and development expenses, including general research and development spending, were $14,857,095 for fiscal 2019 compared to $32,566,217 for fiscal 2018. Fiscal 2019 costs primarily relate to our MC4r and other preclinical programs along with an additional Phase 1 study for Vyleesi. Fiscal 2018 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, PL3994, PL8177, MC1r, MC4r and other preclinical projects were $10,129,640 and $27,449,494 in fiscal 2019 and fiscal 2018, respectively. Spending to date was 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, PL8177 and PL3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which was $4,727,455 and $5,116,723 in fiscal 2019 and fiscal 2018, respectively. The decrease in general research and development spending is primarily attributable to lower stock-based compensation in fiscal 2019.

Cumulative spending from inception to June 30, 2019 was approximately $310,200,000 on our Vyleesi program and approximately $142,000,000 on all our other programs (which include PL8177, PL9643, other melanocortin receptor agonists, NPR 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 $9,699,061 for fiscal 2019 compared to $8,641,976 for fiscal 2018. The increase in general and administrative expenses is primarily attributable to an increase in compensation expense.

Other Income (Expense) – Total other income, net was $28,707 for fiscal 2019 and total other expenses, net was $1,141,351 for fiscal 2018. For fiscal 2019, we recognized $446,268 of investment income offset by $417,561 of interest expense primarily related to our venture debt. For fiscal 2018, we recognized $1,452,014 of interest expense primarily related to our venture debt, offset by $310,663 of investment income. The decrease in interest expense relates to our paying down of the venture debt.

Income Taxes – For fiscal 2019, the Company recorded no income tax expense as a result of the utilization of net operating losses that were subject to a full valuation allowance.

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 generally 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 generate 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.

In addition, the COVID-19 pandemic may negatively impact our operations, including possible effects on our financial condition, ability to access the capital markets on attractive terms or at all, liquidity, operations, suppliers, industry, and workforce. We will continue to evaluate the impact that these events could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2021 and beyond.

During fiscal 2020, net cash provided by operating activities was $41,326,415 compared to net cash used in operating activities of $21,782,841 in fiscal 2019 and net cash provided by operating activities of $1,703,103 in fiscal 2018. The difference in cash provided by operations in fiscal 2020 compared with cash used in operations in fiscal 2019 and compared with cash provided by operating activities in fiscal 2018 was primarily related to the timing of the receipt of payments related to revenue recorded for the AMAG License Agreement, including for the FDA's approval of Vyleesi.

During fiscal 2020, net cash used in investing activities consisted of $62,880 compared to $36,139 during fiscal 2019, which consisted of the acquisition of equipment. 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 2020 net cash used in financing activities was $1,921,687 which consisted of payment on notes payable obligations of $832,851, repurchase and cancellation of outstanding warrants of $2,547,466 and payment of withholding taxes related to restricted stock units of $122,868 offset by net proceeds from the sale of common stock of $1,581,498 in our "at-the-market" offering program. During fiscal 2019, net cash provided by financing activities was $27,329,231 which consisted of proceeds from the sale of common stock of $33,136,060 and proceeds from the exercise of common stock warrants of $808,934 offset by payment of withholding taxes related to restricted stock units and stock options of $115,763 and payment of debt obligations of $6,500,000. 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.

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 develop the capability to market and distribute Vyleesi in the United States and to complete our planned product development efforts. Continued operations are dependent upon our ability to generate future income from sales of Vyleesi in the United States and from existing licenses, including royalties and milestones, to complete equity or debt financing activities and enter into additional licensing or collaboration arrangements. As of June 30, 2020, our cash and cash equivalents were $82,852,270 with current liabilities of $3,927,553.

We intend to utilize existing capital resources for general corporate purposes and working capital, including establishing marketing and distribution capabilities for Vyleesi in the United States and 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 cash and cash equivalents as of June 30, 2020 will be sufficient to fund our current operating plans through at least September 2021. We will need additional funding to complete 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.

We had a net loss for fiscal 2020 of $22,426,023. We may not attain 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 to develop marketing and distribution capability for Vyleesi in the United States and continue to develop our MC1r and natriuretic peptide product candidates. 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, 2020:

	Payments due by Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating leases	$ 1,434,330	$ 355,164	$ 556,818	$ 522,348	$ -

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, 2020 and 2019, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity (deficiency), and cash flows for each of the years in the three-year period ended June 30, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended June 30, 2020, in conformity with U.S. generally accepted accounting principles.

Changes in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for revenue as of July 1, 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*.

Also as discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for leases as of July 1, 2019 due to the adoption of ASU No. 2016-02, *Leases.*

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 25, 2020

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Balance Sheets

	June 30, 2020	June 30, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,852,270	$ 43,510,422
Accounts receivable	-	60,265,970
Prepaid expenses and other current assets	738,216	637,289
Total current assets	83,590,486	104,413,681
Property and equipment, net	140,216	141,539
Right-of-use assets	1,266,132	-
Other assets	56,916	179,916
Total assets	$ 85,053,750	$ 104,735,136
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 715,672	$ 504,787
Accrued expenses	2,899,097	2,848,692
Notes payable, net of discount	-	332,896
Short-term operating lease liabilities	312,784	-
Other current liabilities	-	499,517
Total current liabilities	3,927,553	4,185,892
Long-term operating lease liabilities	953,348	-
Total liabilities	4,880,901	4,185,892
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock of $0.01 par value – authorized 10,000,000 shares; shares issued and outstanding designated as follows:		
Series A Convertible: authorized 264,000 shares: issued and outstanding 4,030 shares as of June 30, 2020 and June 30, 2019	40	40
Common stock of $0.01 par value – authorized 300,000,000 shares:		
issued and outstanding 229,258,400 shares as of June 30, 2020 and 226,815,363 shares as of June 30, 2019	2,292,584	2,268,154
Additional paid-in capital	396,079,127	394,053,929
Accumulated deficit	(318,198,902)	(295,772,879)
Total stockholders' equity	80,172,849	100,549,244
Total liabilities and stockholders' equity	$ 85,053,750	$ 104,735,136

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,		
	2020	**2019**	**2018**
REVENUES			
License and contract	$ 117,989	$ 60,300,476	$ 67,134,758
OPERATING EXPENSES			
Research and development	13,959,397	14,857,095	32,566,217
General and administrative	9,765,372	9,699,061	8,641,976
Total operating expenses	23,724,769	24,556,156	41,208,193
(Loss) income from operations	(23,606,780)	35,744,320	25,926,565
OTHER INCOME (EXPENSE)			
Investment income	1,200,898	446,268	310,663
Interest expense	(20,141)	(417,561)	(1,452,014)
Total other income (expense), net	1,180,757	28,707	(1,141,351)
(Loss) income before income taxes	(22,426,023)	35,773,027	24,785,214
Income tax expense	-	-	(82,500)
NET LOSS (INCOME)	$ (22,426,023)	$ 35,773,027	$ 24,702,714
Basic net (loss) income per common share	$ (0.10)	$ 0.17	$ 0.12
Diluted net (loss) income per common share	$ (0.10)	$ 0.16	$ 0.12
Weighted average number of common shares outstanding used in computing basic net (loss) income per common share	234,684,776	207,670,607	198,101,060
Weighted average number of common shares outstanding used in computing diluted net (loss) income per common share	234,684,776	217,133,374	207,007,558

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

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Comprehensive (Loss) Income

	Year Ended June 30,		
	2020	2019	2018
Net (loss) income	$ (22,426,023)	$ 35,773,027	$ 24,702,714
Other comprehensive income:			
Unrealized gain on available-for-sale investments	-	-	590
Total comprehensive (loss) income	$ (22,426,023)	$ 35,773,027	$ 24,703,304

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 (Loss)	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Total
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
Cumulative effect of accounting change	-	-	-	-	-	-	500,000	500,000
Stock-based compensation	-	-	327,692	3,277	3,478,800	-	-	3,482,077
Sale of common stock , net of costs	-	-	24,785,814	247,858	32,888,202	-	-	33,136,060
Withholding taxes related to restricted stock units	-	-	(67,038)	(670)	(65,322)	-	-	(65,992)
Withholding taxes related to stock options	-	-	(37,994)	(380)	(49,391)	-	-	(49,771)
Warrant exercises	-	-	1,115,333	11,153	797,781	-	-	808,934
Option exercises	-	-	137,351	1,374	(1,374)	-	-	-
Net income	-	-	-	-	-	-	35,773,027	35,773,027
Balance, June 30, 2019	4,030	40	226,815,363	2,268,154	394,053,929	-	(295,772,879)	100,549,244
Stock-based compensation	-	-	614,117	6,141	3,132,323	-	-	3,138,464
Sale of common stock , net of costs	-	-	1,895,934	18,959	1,562,539	-	-	1,581,498
Withholding taxes related to restricted stock units	-	-	(93,875)	(939)	(121,929)	-	-	(122,868)
Warrant repurchases	-	-	-	-	(2,547,466)	-	-	(2,547,466)
Warrant Exercises	-	-	26,861	269	(269)	-	-	-
Net loss	-	-	-	-	-	-	(22,426,023)	(22,426,023)
Balance June 30, 2020	4,030	$ 40	229,258,400	$ 2,292,584	$396,079,127	$ -	$(318,198,902)	$80,172,849

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,		
	2020	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) Income	$ (22,426,023)	$ 35,773,027	$ 24,702,714
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:			
Depreciation and amortization	64,203	58,635	56,569
Non-cash interest expense	438	51,234	175,493
Decrease in right-of-use asset	298,558	-	-
Stock-based compensation	3,138,464	3,482,077	3,518,351
Deferred income tax benefit	-	-	(500,000)
Changes in operating assets and liabilities:			
Accounts receivable	60,265,970	(60,265,970)	15,116,822
Prepaid expenses and other assets	22,073	35,399	715,533
Accounts payable	210,885	(1,718,906)	672,326
Accrued expenses	50,405	745,671	(8,393,698)
Deferred revenue	-	-	(34,550,572)
Operating lease liabilities	(298,558)	-	-
Other liabilities	-	55,992	189,565
Net cash provided by (used in) operating activities	41,326,415	(21,782,841)	1,703,103
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from matured investments	-	-	250,000
Purchases of property and equipment	(62,880)	(36,139)	(22,451)
Net cash (used in) provided by investing activities	(62,880)	(36,139)	227,549
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payment on capital lease obligations	-	-	(14,324)
Payment of withholding taxes related to restricted stock units	(122,868)	(115,763)	(45,165)
Payment on notes payable obligations	(832,851)	(6,500,000)	(8,000,000)
Proceeds from the exercise of stock options	-	-	159,881
Proceeds from exercise of common stock warrants	-	808,934	2,511,029
Warrant repurchases	(2,547,466)	-	-
Proceeds from the sale of common stock, net of costs	1,581,498	33,136,060	1,257,774
Net cash (used in) provided by financing activities	(1,921,687)	27,329,231	(4,130,805)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	39,341,848	5,510,251	(2,200,153)
CASH AND CASH EQUIVALENTS, beginning of year	43,510,422	38,000,171	40,200,324
CASH AND CASH EQUIVALENTS, end of year	$ 82,852,270	$ 43,510,422	$ 38,000,171
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash paid for interest	$ 19,222	$ 354,456	$ 1,084,158
Cash paid for income taxes	-	-	500,000

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

(1) ORGANIZATION

Nature of Business - 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. The Company's product candidates are targeted, receptor-specific therapeutics for the treatment of diseases with significant unmet medical need and commercial potential.

Melanocortin Receptor System. The melanocortin receptor ("MCr") system is hormone driven, with effects on food intake, metabolism, sexual function, inflammation and immune system responses. 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.

The Company's lead product, Vyleesi®, was approved by the U.S. Food and Drug Administration ("FDA") in June 2019 and was being marketed in North America by AMAG Pharmaceuticals, Inc. ("AMAG") for the treatment of hypoactive sexual desire disorder ("HSDD") in premenopausal women pursuant to a license agreement between them for Vyleesi for North America, which was entered into on January 8, 2017 (the "AMAG License Agreement"). As disclosed in Note 4, AMAG announced its plan in January 2020 to divest Vyleesi and another product. As disclosed in Note 17, subsequent to fiscal year end AMAG and the Company entered into an agreement to terminate the AMAG License Agreement.

The Company's new product development activities focus primarily on MC1r agonists, with potential to treat inflammatory and autoimmune diseases such as dry eye disease, which is also known as keratoconjunctivitis sicca, uveitis, diabetic retinopathy and inflammatory bowel disease. The Company believes that the MC1r agonist peptides in development 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. The Company is also developing peptides that are active at more than one melanocortin receptor, and MC4r peptide and small molecule agonists with potential utility in obesity and metabolic-related disorders, including rare disease and orphan indications.

Natriuretic Peptide Receptor System. The natriuretic peptide receptor ("NPR") system regulates cardiovascular functions, and therapeutic agents modulating this system have potential to treat cardiovascular and fibrotic diseases. The Company has designed and is developing potential NPR candidate drugs 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").

Business Risks 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 develop the capability to market and distribute Vyleesi in the United States and complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company had an accumulated deficit as of June 30, 2020 of $318,198,902 and a net loss for the year ended June 30, 2020 of $22,426,023, and the Company anticipates incurring significant expenses in the future as a result of spending on developing marketing and distribution capabilities for Vyleesi in the United States and 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, 2020, the Company's cash and cash equivalents were $82,852,270 and current liabilities were $3,927,553. Management intends to utilize existing capital resources for general corporate purposes and working capital, including establishing marketing and distribution capabilities for Vyleesi in the United States and preclinical and clinical development of the Company's MC1r and MC4r peptide programs and natriuretic peptide program, and development of other portfolio products.

Management believes that the Company's cash and cash equivalents as of June 30, 2020 will be sufficient to fund our current operating plans through at least September 2021. 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 could be materially adversely affected.

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.

In March 2020, the World Health Organization declared COVID-19, a disease caused by a novel strain of coronavirus, a pandemic. The Company has taken steps to ensure the safety and well-being of its employees and clinical trial patients to comply with guidance from federal, state and local authorities, while working to ensure the sustainability of its business operations as this unprecedented situation continues to evolve. In mid-March, the Company transitioned to a company-wide work from home policy. Business-critical activities continue to be subject to heightened precautions to ensure safety of employees. The Company continues to assess its policies, business continuity plans and employee support.

The Company continues to evaluate the impact of COVID-19 on the healthcare system and work with contract research organizations supporting its clinical, research, and development programs to mitigate risk to patients and its business and community partners, taking into account regulatory, institutional, and government guidance and policies.

The Company receives a royalty on sales of Vyleesi by our licensees. We have licensed third parties to sell Vyleesi in China and Korea. The COVID-19 coronavirus could adversely impact the time required to obtain regulatory approvals to sell Vyleesi in China and Korea, which would delay when the Company receives royalty income from sales in those countries.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and it has the potential to materially adversely affect its business, financial condition and results of operations and cashflows during fiscal 2021 and beyond.

Concentrations – Concentrations in the Company's assets and operations subject it to certain related risks. Financial instruments that subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents. The Company's cash and cash equivalents are primarily invested in one money market account sponsored by a large financial institution. For the year ended June 30, 2020, the Company reported $117,989 in revenue, solely related to the AMAG License Agreement (Note 4). For the years ended June 30, 2019 and 2018, the Company reported $60,300,476, and $62,134,758, respectively, in license and contract revenue related to the AMAG License Agreement. 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.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation – The consolidated financial statements include the accounts of the Company 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 $82,406,697 and $43,381,556 in a money market account at June 30, 2020 and 2019, respectively.

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

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 balances insured 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.

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 – In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASC Topic 606"), which, along with amendments from 2015 and 2016 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. ASC Topic 606 replaced most existing revenue recognition guidance in U.S. GAAP when it became effective.

On July 1, 2018, the Company adopted ASC Topic 606 using the modified retrospective approach, a practical expedient permitted under ASC Topic 606, and applied this approach only to contracts that were not completed as of July 1, 2018. The Company calculated a one-time cumulative transition adjustment of $500,000 which was recorded on July 1, 2018 to the opening balance of accumulated deficit related to the license agreement with Kwangdong Pharmaceutical Co., Ltd. ("Kwangdong") to market Vyleesi in the Republic of Korea (the "Kwangdong License Agreement"), as the Company determined a significant revenue reversal would not occur in a future period. The one-time adjustment consisted of the recognition of $500,000 of deferred revenue.

Revenue Recognition for Periods Prior to July 1, 2018

The Company has generated revenue solely through license and collaboration agreements. Prior to July 1, 2018, the Company recognized revenue in accordance with FASB Accounting Standards Codifications ("ASC") Topic 605-25, *Revenue Recognition for Arrangements with Multiple Elements* , which addressed the determination of whether an arrangement involving multiple deliverables contained more than one unit of accounting. A delivered item within an arrangement was considered a separate unit of accounting only if both of the following criteria were met:

- the delivered item had value to the customer on a stand-alone basis; and
- if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered item was considered probable and substantially in control of the vendor.

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

The Company determined that it was appropriate to recognize such revenue using the input-based proportional method during the period of the Company's development obligations as defined in the AMAG License Agreement. Refer to Note 4 for additional information.

Under 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 had stand-alone value and the upfront payment received by the Company was non-refundable.

Under the Kwangdong License Agreement (Note 6), the Company received consideration in the form of an upfront license fee payment and determined that it was appropriate to record such consideration as deferred revenue because the upfront payment received by the Company is subject to certain refund provisions.

Revenue resulting from the achievement of development milestones was recorded in accordance with the accounting guidance for the milestone method of revenue recognition. Amounts received prior to satisfying the revenue recognition criteria were recorded as deferred revenue on the Company's consolidated balance sheet.

Revenue Recognition for Periods Commencing July 1, 2018

For licenses of intellectual property, the Company assesses, at contract inception, whether the intellectual property is distinct from other performance obligations identified in the arrangement. If the licensing of intellectual property is determined to be distinct, revenue is recognized for nonrefundable, upfront license fees when the license is transferred to the customer and the customer can use and benefit from the license. If the licensing of intellectual property is determined not to be distinct, then the license will be bundled with other promises in the arrangement into one performance obligation. The Company needs to determine if the bundled performance obligation is satisfied over time or at a point in time. If the Company concludes that the nonrefundable, upfront license fees will be recognized over time, the Company will need to assess the appropriate method of measuring proportional performance.

Regulatory milestone payments are excluded from the transaction price due to the inability to estimate the probability of reversal. Revenue relating to achievement of these milestones is recognized in the period in which the milestone is achieved.

Sales-based royalty and milestone payments resulting from customer contracts solely or predominately for the license of intellectual property will only be recognized upon occurrence of the underlying sale or achievement of the sales milestone in the future and such sales-based royalties and milestone payments will be recognized in the same period earned.

The Company recognizes revenue for reimbursements of research and development costs under collaboration agreements as the services are performed. The Company records these reimbursements as revenue and not as a reduction of research and development expenses as the Company is the principal in the research and development activities based upon its control of such activities, which is considered part of its ordinary activities.

Development milestone payments are generally due 30 business days after the milestone is achieved. Sales milestone payments are generally due 45 business days after the calendar year in which the sales milestone is achieved. Royalty payments are generally due on a quarterly basis 20 business days after being invoiced.

The cumulative effect of applying ASC Topic 606 to the Company's consolidated balance sheet was as follows:

	Balance at June 30, 2018	Net Adjustment	Balance at July 1, 2018
Deferred revenue	$ 500,000	$ (500,000)	$ -
Accumulated deficit	(332,045,906)	500,000	(331,545,906)

ASC Topic 606 did not have an impact on the Company's consolidated statements of operations or cash flows.

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 the Company's development activities. The Company reviews the activities performed under all contracts each quarter and accrues expenses and the amount of any reimbursement to be received from its 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 the Company does not identify services performed for it but not billed by the service-provider, or if it underestimates or overestimates the value of services performed as of a given date, reported expenses will be understated or overstated.

Stock-Based Compensation – The Company charges to expense the fair value of stock options and other equity awards granted. Compensation costs for stock-based awards with time-based vesting are determined using the quoted market price of the Company's common stock on the date of grant or for stock options, the value determined utilizing the Black-Scholes option pricing model, and are recognized 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 or for stock options, the value is determined utilizing the Black Scholes option pricing model, and are recognized based on the probability of achievement of the performance condition over the service period. Forfeitures are recognized as they occur.

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 and continues to maintain a full valuation allowance against its deferred tax assets based on the history of losses incurred.

On March 27, 2020, the President of the United States signed into law the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which provides emergency economic assistance for American workers, families and businesses affected by the COVID-19 pandemic. The economic relief package includes government loan enhancement programs and various tax provisions to help improve liquidity for American businesses. Based on management's evaluation of the CARES Act tax provisions, there is no material impact to the Company for the year ended June 30, 2020. Management will continue monitor any effects that may arise from the CAREs Act.

Net (Loss) Income per Common Share - Basic and diluted (loss) income 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 Company's 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 were considered in the computation of basic and diluted net (loss) income per common share. As of November 21, 2017, all warrants exercisable for nominal value had been converted into common stock.

The following table is a reconciliation of net (loss) income and the shares used in calculating basic and diluted net (loss) income per common share for the years ended June 30, 2020, 2019 and 2018:

	Year Ended June 30,		
	2020	2019	2018
Net (loss) income	$ (22,426,023)	$ 35,773,027	$ 24,702,714
Denominator:			
Weighted average common shares - Basic	234,684,776	207,670,607	198,101,060
Effect of dilutive shares:			
Common stock equivalents arising from stock options, warrants and conversion of preferred stock	-	7,142,309	6,752,604
Restriced stock units	-	2,320,458	2,153,874
Weighted average common shares - Diluted	234,684,776	217,133,374	207,007,538
Net (loss) income per common share:			
Basic	$ (0.10)	$ 0.17	$ 0.12
Diluted	$ (0.10)	$ 0.16	$ 0.12

For the year ended June 30, 2020, no additional common shares were added to the computation of diluted EPS because to do so would have been anti-dilutive. The potential number of common shares excluded from diluted EPS during the year ended June 30, 2020 was 40,890,091.

As of June 30, 2019 and 2018 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 6,130,876 and 5,197,592, respectively, being excluded from the weighted average number of common shares outstanding used in computing diluted net income per common share because they were anti-dilutive during the period or the minimum performance requirements or market conditions had not been met.

Included in the weighted average common shares used in computing basic and diluted net (loss) income per common share are 7,127,362, 6,138,166, and 3,140,499 vested restricted stock units that had not been issued as of June 30, 2020, 2019 and 2018, respectively, due to a provision in the restricted stock unit agreements to delay delivery.

(3) NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In August 2020, the FASB issued ASU No. 2020-06, *Debt (Topic 470) and Derivatives and Hedging (Topic 815): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The amendments in this update address issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The guidance is effective for public entities for fiscal years beginning after December 15, 2021, and for interim periods within those fiscal years, with early adoption permitted. The guidance is applicable to the Company beginning July 1, 2022. The Company is currently evaluating the potential effects of this guidance on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The guidance is effective for public entities for fiscal years beginning after December 15, 2020, and for interim periods within those fiscal years, with early adoption permitted. The guidance is applicable to the Company beginning July 1, 2021. The Company is currently evaluating the potential effects of this guidance on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606.* This update provides clarification on the interaction between Revenue Recognition (Topic 606) and Collaborative Arrangements (Topic 808), including the alignment of unit of account guidance between the two topics. The guidance is effective for public entities for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, with early adoption permitted. The guidance is applicable to the Company beginning July 1, 2020. The adoption of ASU No. 2018-18 is not expected to have a material impact on the Company's consolidated financial statements.

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 adopted this guidance during the year ended June 30, 2019. The adoption of this standard did not have a material impact on the Company's 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, 2023 with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

On July 1, 2019, the Company adopted the requirements of ASU No.2016-02, *Leases* ("Topic 842"). The objective of this ASU, along with several related ASUs issued subsequently, is to increase transparency and comparability between organizations that enter into lease agreements. For lessees, the key difference of the new standard from the previous guidance ("Topic 840") is the recognition of a right-of-use ("ROU") asset and lease liability on the balance sheet. The most significant change is the requirement to recognize ROU assets and lease liabilities for leases classified as operating leases. The standard requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. As part of the transition to the new standard, the Company elected to measure and recognize leases that existed at July 1, 2019 using a modified retrospective approach, including the option to not restate comparative periods. For leases existing at the effective date, the Company elected the package of three transition practical expedients and therefore did not reassess whether an arrangement is or contains a lease, did not reassess lease classification, and did not reassess what qualifies as an initial direct cost. Additionally, the Company elected, as practical expedients, not separating lease and non-lease components for all of its leases and the short-term lease recognition exemption for all of its leases that qualify. The Company did not elect the use of the hindsight practical expedient. The adoption of Topic 842 resulted in the recognition of an operating ROU asset and operating lease liability of $225,134 as of July 1, 2019. The adoption did not have a material impact on the consolidated statements of operations, stockholder's equity and cash flows for year ended June 30, 2020.

At lease inception, the Company determines whether an arrangement is or contains a lease. Operating leases are included in operating lease ROU assets, current operating lease liabilities, and noncurrent operating lease liabilities in the consolidated financial statements. ROU assets represent the Company's right to use leased assets over the term of the lease. Lease liabilities represent the Company's contractual obligation to make lease payments over the lease term. For operating leases, ROU assets and lease liabilities are recognized at the commencement date. The lease liability is measured as the present value of the lease payments over the lease term. The Company uses the rate implicit in the lease if it is determinable. When the rate implicit in the lease is not determinable, the Company uses an estimate based on a hypothetical rate provided by a third party as the Company currently does not have issued debt. Operating ROU assets are calculated as the present value of the remaining lease payments plus unamortized initial direct costs plus any prepayments less any unamortized lease incentives received. Lease terms may include renewal or extension options to the extent they are reasonably certain to be exercised. The assessment of whether renewal or extension options are reasonably certain to be exercised is made at lease commencement. Factors considered in determining whether an option is reasonably certain of exercise include, but are not limited to, the value of any leasehold improvements, the value of renewal rates compared to market rates, and the presence of factors that would cause incremental costs to the Company if the option were not exercised. Lease expense is recognized on a straight-line basis over the lease term. The Company has elected not to recognize an ROU asset and obligation for leases with an initial term of twelve months or less. The expense associated with short term leases is included in general and administrative expense in the statement of operations. To the extent a lease arrangement includes both lease and non-lease components, the Company has elected to account for the components as a single lease component.

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 Company adopted this guidance during the year ended June 30, 2019. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

(4) AGREEMENT WITH AMAG

On January 8, 2017, the Company entered into the AMAG License Agreement pursuant to which the Company granted 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 the 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.

Following the satisfaction of certain conditions to closing, the AMAG License Agreement became effective on February 2, 2017, and AMAG paid the Company $60,000,000 as a one-time initial payment. Under 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 development and regulatory activities necessary to file a New Drug Application ("NDA") for Vyleesi for HSDD in the United States.

The Company determined there was 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 AMAG License Agreement, represented a combined unit of accounting which totaled $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, 2020, 2019, and 2018, license and contract revenue included additional billings for AMAG related Vyleesi costs of $117,989, $1,151,243, and $707,342 respectively.

On June 4, 2018, the FDA accepted the Vyleesi NDA for filing. The FDA's acceptance triggered a $20,000,000 milestone payment to the Company from AMAG. As a result, the Company recognized $20,000,000 in revenue related to regulatory milestones in fiscal 2018. On June 21, 2019, the FDA granted approval of Vyleesi for use in the United States. The FDA's approval triggered a $60,000,000 milestone payment to the Company from AMAG. As a result, the Company recognized $60,000,000 in revenue related to regulatory milestones in fiscal 2019. In addition , pursuant to the terms and subject to the conditions in the AMAG License Agreement, the Company was eligible to receive from AMAG certain sales milestone payments and royalties on net sales of the products. As of June 30, 2019, no revenue was recognized related to these payments and royalties.

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, as defined, paid or to be 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 and recorded as an expense upon the closing of the licensing transaction. This amount was credited toward amounts that were to become due to Greenhill, provided that the aggregate fee payable to Greenhill would not be less than 2% of all proceeds and consideration, as defined, paid or to be paid to the Company by AMAG in connection with the AMAG License Agreement. On November 21, 2019, the Company and Greenhill mutually agreed to terminate the engagement agreement. As a result, the Company made a final payment to Greenhill of $625,000, which was recorded in general and administrative expenses during the year ended June 30, 2020. The Company has no future payment obligations to Greenhill.

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

On January 9, 2020, AMAG announced plans to divest Vyleesi and Intrarosa® (prasterone), both women's healthcare products. While AMAG indicated that it has received preliminary expressions of interest to acquire or sublicense rights to these products, there were no public disclosures of any potential licensees of AMAG's rights to Vyleesi in North America. After FDA approval of Vyleesi in June 2019, AMAG launched Vyleesi nationally in September 2019 through select specialty pharmacies with its maternal and women's health sales force.

As disclosed in Note 17, effective July 24, 2020, the Company and AMAG entered into an agreement to mutually terminate the AMAG License Agreement.

(5) AGREEMENT WITH FOSUN:

On September 6, 2017, the Company entered into a license agreement with Fosun ("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. The Company 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 was recorded as non-current deferred revenue at June 30, 2018. On July 1, 2018, in conjunction with the adoption of ASC Topic 606, a one-time transition adjustment of $500,000 was recorded to the opening balance of accumulated deficit as the Company determined a significant revenue reversal would not occur in a future period. The Company will receive a $3,000,000 milestone payment based on the first commercial sale in Korea. The Company 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, 2020	June 30, 2019
Clinical / regulatory costs	$ 43,625	$ 61,798
Insurance premiums	84,741	87,937
Other	609,850	487,554
	$ 738,216	$ 637,289

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

The following table provides the assets carried at fair value:

	Carrying Value	Quoted prices in active markets (Level 1)	Other quoted/observable inputs (Level 2)	Significant unobservable inputs (Level 3)
June 30, 2020:				
Money Market Account	$ 82,406,697	$ 82,406,697	$ -	$ -
June 30, 2019:				
Money Market Account	$ 43,381,556	$ 43,831,556	$ -	$ -

(9) LEASES

The Company has operating leases for office and laboratory space, which expire on June 30, 2025 and June 30, 2021, respectively. The Company also has operating leases for copier equipment that expire October 15, 2021 and phone equipment that expires on June 30, 2023.

The components of lease expense are as follows:

Lease cost	Year ended June 30, 2020
Operating lease cost	$ 209,226
Variable lease cost	71,297
Short-term lease cost	18,120
Total lease cost	$ 298,643

Supplemental balance sheet information related to leases was as follows:

	June 30, 2020
Operating lease ROU asset	$ 1,266,132
Short-term operating lease liabilities	$ 312,784
Long-term operating lease liabilities	953,348
	$ 1,266,132

Supplemental lease term and discount rate information related to leases was as follows:

Weighted-average remaining lease term (years)	4.6
Weighted-average discount rate	5.51%

Supplemental cash flow information related to leases was as follows:

	Year ended June 30, 2020
Cash paid for the amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	$ 318,244
Supplemental non-cash information on lease liabilities arisng from obtaining right-of-use assets:	
Right-of-use assets obtained in exchange for new lease obligation	$ 1,339,556

The following table summarizes the maturity of the Company's operating lease liability as of June 30, 2020:

Year Ending June 30	
2021	$ 355,164
2022	277,062
2023	279,756
2024	257,316
2025	265,032
Less imputed interest	(168,198)
Total	$ 1,266,132

As of June 30, 2019, the Company had $225,120 in future lease payments for the year ending June 30, 2020 under ASC Topic 840. For the years ended June 30, 2019 and 2018, rent expense was $285,453 and $292,411, respectively.

(10) PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consists of the following:

	June 30, 2020	June 30, 2019
Office equipment	$ 1,193,162	$ 1,193,162
Laboratory equipment	648,673	585,795
Leasehold improvements	751,226	751,226
	2,593,061	2,530,183
Less: Accumulated depreciation and amortization	(2,452,845)	(2,388,644)
	$ 140,216	$ 141,539

(11) ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30, 2020	June 30, 2019
Clinical / regulatory costs	$ 1,722,729	$ 943,721
Other research related expenses	586,185	1,361,414
Professional services	217,662	317,500
Other	372,521	226,057
	$ 2,899,097	$ 2,848,692

(12) NOTES PAYABLE:

Notes payable consist of the following:

	June 30, 2019
Notes payable under venture loan	$ 333,333
Unamortized related debt discount	(295)
Unamortized debt issuance costs	(142)
Notes payable	$ 332,896

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 was a four-year senior secured term loan that bore interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50%, and provided 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 was amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and included in additional paid-in capital on the Company’s balance sheet. In addition, a final incremental payment of $500,000 was due on January 1, 2019, or upon early repayment of the loan. This final incremental payment was accreted to interest expense over the term of the related debt and included in other liabilities on the consolidated balance sheet. The Company incurred $209,367 of costs in connection with the loan. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the three months ended December 31, 2018, the loan matured, and on December 31, 2018, the Company made the final incremental payment of $500,000.

On July 2, 2015, the Company closed on a $10,000,000 venture loan led by Horizon. The debt facility was a four-year senior secured term loan that bore interest at a floating coupon rate of one-month LIBOR (floor of 0.50%) plus 8.50% and provided 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 recorded a debt discount of $305,196 equal to the fair value of these warrants at issuance, which were amortized to interest expense over the term of the related debt. This debt discount was offset against the note payable balance and was included in additional paid-in capital on the Company's balance sheet. In addition, a final incremental payment of $500,000 was due on August 1, 2019. This final incremental payment was accreted to interest expense over the term of the related debt and was included in other current liabilities on the consolidated balance sheet as of June 30, 2019. The Company incurred $146,115 of costs in connection with the loan agreement. These costs were capitalized as deferred financing costs and were offset against the note payable balance. These debt issuance costs were amortized to interest expense over the term of the related debt. During the year ended June 30, 2020, the loan matured, and on July 31, 2019, the Company made the final incremental payment of $500,000.

(13) COMMITMENTS AND CONTINGENCIES

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, 2020, 2019, and 2018 Company contributions were $116,807, $170,643, and $166,962, 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, 2020, 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, 2020, the Series A Conversion Price was $6.10, so each share of Series A Convertible Preferred Stock is currently convertible into approximately 16.4 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, 2020. 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 June 21, 2019 and April 20, 2018, the Company entered into equity distribution agreements with Canaccord Genuity LLC ("Canaccord") (the "2019 Equity Distribution Agreement" and the "2018 Equity Distribution Agreement", respectively), 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 2018 Equity Distribution Agreement and related prospectus was limited to sales of up to an aggregate maximum $25.0 million of shares of the Company's common stock, and the 2019 Equity Distribution Agreement and related prospectus is limited to sales of up to an aggregate maximum $40.0 million of shares of the Company's common stock. The Company pays Canaccord 3.0% of the gross proceeds as a commission.

Proceeds raised under the 2019 Equity Distribution Agreement are as follows:

	Year Ended June 30, 2020		Year Ended June 30, 2019		Cumulative from inception	
	Shares	Proceeds	Shares	Proceeds	Shares	Proceeds
Gross proceeds	1,895,934	$ 1,723,195	7,564,575	10,607,047	9,460,509	$12,330,242
Fees	-	(51,697)	-	(318,211)	-	(369,908)
Expenses	-	(90,000)	-		-	(90,000)
Net proceeds	**1,895,934**	**$ 1,581,498**	**7,564,575**	**$10,288,836**	**9,460,509**	**$11,870,334**

Proceeds raised under the 2018 Equity Distribution are as follows:

	Year Ended June 30, 2019		Year Ended June 30, 2018		Cumulative from inception	
	Shares	Proceeds	Shares	Proceeds	Shares	Proceeds
Gross proceeds	17,221,239	23,553,838	1,283,754	1,446,159	18,504,993	$24,999,997
Fees	-	(706,615)	-	(43,385)	-	(750,000)
Expenses	-	-	-	(145,000)	-	(145,000)
Net proceeds	**17,221,239**	**$22,847,223**	**1,283,754**	**$ 1,257,774**	**18,504,993**	**$24,104,997**

As of June 30, 2019, the 2018 Equity Distribution agreement is completed.

Stock Purchase Warrants – On September 13, 2019, the Company's Board of Directors approved a plan to offer to purchase and terminate certain outstanding common stock purchase warrants through privately negotiated transactions. The purchase and termination program has no time limit and may be suspended for periods or discontinued at any time.

During the year ended June 30, 2020, the Company entered into several warrant termination agreements to repurchase and cancel the following previously issued Series F, Series H, and Series J warrants for the following aggregate buyback prices:

	Year Ended June 30, 2020	
	Warrants	Buyback price
Series F Warrants	297,352	$ 62,712
Series H Warrants	1,466,432	577,373
Series J Warrants	4,774,889	1,907,381
	6,538,673	$ 2,547,466

During the year ended June 30, 2020, the Company issued 26,861 shares of common stock upon the cashless exercise provisions of 666,666 Series D warrants at an exercise price of $0.75 per share.

As of June 30, 2020, the Company had outstanding warrants exercisable for shares of common stock as follows:

Descripton	Shares of Common Stock	Exercise Price per Share	Latest Termination Date
Series F warrants*	1,894,429	$ 0.91	July 2, 2020**
Series G warrants	549,450	0.91	July 2, 2020**
Series H warrants *	7,974,881	0.70	August 4, 2021
Financial services warrants	25,000	0.70	August 4, 2021
Series J warrants*	4,639,614	0.80	December 6, 2021
	15,083,374		

* Subject to a limitation on their exercise if the holder and its affiliates would beneficially own 9.99% of the total number of the Company's shares of common stock following such exercise.
** Expired unexercised on July 2, 2020.

During the year ended June 30, 2019, the Company received $225,600 and issued 282,000 shares of common stock pursuant to the exercise of warrants at an exercise price of $0.80 per share. The Company also received $583,334 and issued 833,333 shares of common stock pursuant to the exercise of warrants at an exercise price of $0.70 per share.

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.

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, June 26, 2018, and again at the annual meeting of stockholders held on June 25, 2020. The 2011 Stock Incentive Plan, as amended, 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 42,500,000 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, 2020, 5,552,149 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, 2020, 2019, and 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
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	
Granted	2,340,200	1.34		
Forfeited	(280,362)	0.62		
Exercised	(270,500)	0.64		
Expired	(129,150)	1.77		
Outstanding - June 30, 2019	14,435,650	0.85	7.3	
Granted	5,779,850	0.58		
Forfeited	(235,950)	0.86		
Exercised	-	-		
Expired	(77,100)	2.72		
Outstanding - June 30, 2020	19,902,450	$ 0.76	7.4	$ 380,514
Exercisable at June 30, 2020	10,366,100	$ 0.79	5.8	$ 299,137
Expected to vest at June 30, 2020	9,536,350	$ 0.74	9.2	$ 81,377

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

Included in the options outstanding above are 1,075,000 and 117,500 performance-based options granted in December 2017 to 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 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 options was $602,760. The Company amortized 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 and 50% of the target number of options vested in June 2019 upon FDA approval of Vyleesi.

For the years ended June 30, 2020, 2019 and 2018, 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, 2020, 2019, and 2018 were as follows:

	Year Ended June 30,		
	2020	2019	2018
Risk-free interest rate	0.5%	1.9%	1.8%
Volatility factor	67.1%	69.3%	52.6%
Dividend yield	0%	0%	0%
Expected option life (years)	6.1	6.1	6.0
Weighted average grant date fair value	$ 0.33	$ 0.85	$ 0.58

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, 2020, 2019, and 2018, the Company recorded stock-based compensation related to stock options of $1,372,931, $1,116,350, and $1,131,895, respectively. As of June 30, 2020, there was $3,958,195 of unrecognized compensation cost related to unvested options, which is expected to be recognized over a weighted-average period of 3.1 years.

During fiscal 2019, the terms of certain options were modified to accelerate vesting and extend the date to exercise the options. As a result, the Company recorded additional stock-based compensation of $111,499.

In connection with the cashless exercise of stock options during the year ended June 30, 2019, the Company withheld 37,994 shares with aggregate value of $49,771 in satisfaction of minimum tax withholding obligations.

Restricted Stock Units – The following table summarizes restricted stock award activity for the years ended June 30, 2020, 2019 and 2018:

	Year Ended June 30,		
	2020	2019	2018
Outstanding at beginning of year	10,327,833	9,323,876	5,209,617
Granted	3,397,950	1,517,450	4,914,550
Forfeited	(123,438)	(182,351)	(5,250)
Vested	(636,775)	(331,142)	(795,041)
Outstanding at end of year	12,965,570	10,327,833	9,323,876

For the years ended June 30, 2020, 2019 and 2018 the Company recorded stock-based compensation related to restricted stock units of $1,765,533, $2,143,640, and $2,386,456, respectively.

During fiscal 2019, the terms of certain restricted stock units were modified to accelerate vesting. As a result, the Company recorded additional stock-based compensation of $110,589.

Included in outstanding restricted stock units in the table above are 7,127,362 vested shares that have not been issued as of June 30, 2020 due to a provision in the restricted stock unit agreements to delay delivery.

Time-based restricted stock units granted to the Company's executive officers, employees and non-employee directors generally vest over 48 months, 48 months, and 12 months, respectively.

In June 2020, the Company granted 1,203,500 performance-based restricted stock units to its executive officers and 113,484 performance-based restricted stock units to other employees which vest during a performance period ending June 24, 2024. The performance-based restricted stock units vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials and licensing of Vyleesi in additional countries or regions.

In June 2019, the Company granted 438,000 performance-based restricted stock units to its executive officers and 182,725 performance-based restricted stock units to other employees which vest during a performance period ending June 24, 2023. The performance-based restricted stock units vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials and licensing of Vyleesi in additional countries or regions.

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 amortized 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. Pursuant to the FDA approval of Vyleesi, 50% of the target number of shares vested in June 2019.

In connection with the vesting of restricted share units during the years ended June 30, 2020, 2019, and 2018, the Company withheld 93,875, 67,038 and 27,465 shares, respectively, with aggregate values of $122,868, $65,992, and $20,786 respectively, in satisfaction of minimum tax withholding obligations.

(15) INCOME TAXES

For fiscal 2020 and 2019, the Company recorded no income tax expense as a result of, respectively, an operating loss and the utilization of net operating losses that were subject to a full valuation allowance.

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 the Fosun License Agreement (Note 5) and $82,500, which was withheld in accordance with tax withholding requirements in Korea related to the Kwangdong License Agreement (Note 6). Any potential credit to be received by the Company on its United States tax returns is offset by the Company's valuation allowance. The total income tax expense of $582,500 was offset by an income tax benefit of $500,000, which resulted from the Tax Cuts and Jobs Act (the "2017 Tax Act"), under which Alternative Minimum Tax (" 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, the Company had an income tax receivable of $500,000 from estimated fiscal 2018 AMT that can be refunded in the future. As of June 30, 2019, based upon the filing of the Company's June 30, 2018 tax returns, the Company had a current income tax receivable of $377,000 and a long-term income tax receivable of $123,000. As of June 30, 2020, the Company has a current income tax receivable of $500,000.

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 of June 30, 2020, the Company had state net operating loss carryforwards of approximately $100,000,000, which will expire, if not utilized, between 2034 and 2040, federal net operating loss carryforwards of approximately $82,400,000 and federal research and development credits of approximately $6,400,000, which expire, if not utilized, between 2035 and 2040, and foreign tax credits of $582,500, which expire, if not utilized, in 2028.

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. Based on a history of losses incurred, the Company has recognized a full valuation allowance against its net deferred tax assets during the years ended June 30, 2020, 2019, and 2018.

A sustained period of profitability in the Company's operations is required before it would change its judgment regarding the need for a full valuation allowance against its net deferred tax assets. Accordingly, although the Company was profitable in fiscal 2018 and fiscal 2019 based in part on revenue recorded upon the achievement of certain regulatory milestones, the Company continues to record a full valuation allowance against the net deferred tax assets.

Improvement in the Company's operating results, however, could lead to a reversal of all or some portion of the valuation allowance. Until such time, the use of net operating loss carryforwards and tax credits to offset profits, if any, will reduce the overall level of deferred tax assets subject to valuation allowance.

The Tax Reform Act of 1986 (the "Act") provides for limitation on the use of the Company's 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.

If the Company undergoes a future ownership change or as it completes its Section 382 limitation assessments, 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 and research and development credits.

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, 2020	June 30, 2019
Net operating loss carryforwards	$ 24,321,000	$ 18,724,000
Research and development and AMT tax credits	6,443,000	6,207,000
Foreign tax credits	583,000	583,000
Basis differences in fixed assets and other	1,076,000	1,072,000
	32,423,000	26,586,000
Valuation allowance	(32,423,000)	(26,586,000)
Net deferred tax assets	$ -	$ -

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 2020, 2019 or 2018. As of June 30, 2020 and 2019, the Company had no liabilities for uncertain income tax matters.

(16) CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following tables provide quarterly data for the years ended June 30, 2020 and 2019.

	Three Months Ended			
	June 30, 2020	March 31, 2020	December 31, 2019	September 30, 2019
	(amounts in thousands, except per share data)			
Revenues	$ -	$ -	$ 21	$ 97
Operating expenses	7,390	5,713	5,662	4,960
Other income, net	91	331	397	362
Loss before income taxes	(7,299)	(5,382)	(5,244)	(4,501)
Income taxes	-	-	-	-
Net loss	$ (7,299)	$ (5,382)	$ (5,244)	$ (4,501)
Basic net loss per common share*	$ (0.03)	$ (0.02)	$ (0.02)	$ (0.02)
Diluted net loss per common share*	$ (0.03)	$ (0.02)	$ (0.02)	$ (0.02)
Weighted average number of common shares outstanding used in computing basic net loss per common share	235,394,831	235,322,087	234,923,592	233,113,241
Weighted average number of common shares outstanding used in computing diluted net income loss per common share	235,394,831	235,322,087	234,923,592	233,113,241

* Sum of quarters does not equal annual total due to rounding.

	Three Months Ended			
	June 30, 2019	March 31, 2019	December 31, 2018	September 30, 2018
	(amounts in thousands, except per share data)			
Revenues	$ 60,265	$ -	$ -	$ 35
Operating expenses	8,080	5,763	5,050	5,663
Other income(expense), net	39	36	8	(54)
Income (loss) before income taxes	52,224	(5,727)	(5,042)	(5,682)
Income taxes	-	-	-	-
Net income (loss)	$ 52,224	$ (5,727)	$ (5,042)	$ (5,682)
Basic net income (loss) per common share	$ 0.25	$ (0.03)	$ (0.02)	$ (0.03)
Diluted net income (loss) per common share	$ 0.23	$ (0.03)	$ (0.02)	$ (0.03)
Weighted average number of common shares outstanding used in computing basic net income (loss) per common share	212,253,194	207,016,304	206,487,984	205,009,278
Weighted average number of common shares outstanding used in computing diluted net income (loss) per common share	228,526,106	207,016,304	206,487,984	205,009,278

(17) SUBSEQUENT EVENTS

Effective July 24, 2020, the Company entered into a termination agreement (the "Termination Agreement") with AMAG terminating the AMAG License Agreement. Under the terms of the Termination Agreement, the Company has regained all North American development and commercialization rights for Vyleesi. AMAG made a $12.0 million payment to the Company at closing of the Termination Agreement and will make a $4.3 million payment to the Company on March 31, 2021. The Company will assume all Vyleesi manufacturing agreements, and AMAG will transfer all information, data, and assets related exclusively to Vyleesi, including, but not limited to, existing inventory.

Under the Termination Agreement, AMAG will provide certain transitional services to the Company for a period of time to ensure continued patient access to Vyleesi during the transition back to the Company. The Company will reimburse AMAG for the agreed upon costs of the transition services.

Pursuant to the Termination Agreement, the Company will assume Vyleesi manufacturing contracts with Catalent Belgium S.A. ("Catalent"), a subsidiary of Catalent Pharma Solutions, Inc., to manufacture drug product and prefilled syringes and assemble prefilled syringes into an auto-injector device (the "Catalent Agreement"), Ypsomed AG ("Ypsomed"), to manufacture the auto-injector device (the "Ypsomed Agreement"), and Lonza Ltd. ("Lonza"), to manufacture the active pharmaceutical ingredient peptide (the "Lonza Agreement").

The Company originally entered into the Catalent Agreement on June 20, 2016, and subsequently assigned the Catalent Agreement to AMAG pursuant to the AMAG License Agreement. Upon the Company and AMAG entering into the Termination Agreement, the Catalent Agreement was assigned to the Company. The initial term of the Catalent Agreement is through August 21, 2024, unless earlier terminated in accordance with the terms of the Catalent Agreement. The Catalent Agreement may be terminated immediately by either party if the other party files a petition in bankruptcy, enters into an agreement with its creditors or takes similar action, or if the other party materially breaches any of the provisions of the Catalent Agreement and such breach is not cured within the period outlined in the Catalent Agreement. The Company may terminate the Catalent Agreement if Catalent fails to supply products in accordance with the Catalent Agreement, or if the Company provides notice and pays a termination penalty. There are specified minimum purchase requirements under the Catalent Agreement, and under specified circumstances, termination fees may be payable upon termination of the Catalent Agreement by the Company.

AMAG entered into the Lonza Agreement on June 1, 2018, and upon the Company and AMAG entering into the Termination Agreement, the Lonza Agreement was assigned to the Company. The term of the Lonza Agreement is through December 31, 2022. The Lonza Agreement may be terminated if the other party materially breaches any provisions of the Lonza Agreement and such breach is not cured within the period outlined in the Lonza Agreement, by the Company if the Company is required to withdraw the defined product from the market, or by either party, if the other party becomes insolvent, is dissolved, files a petition in bankruptcy or takes similar action. There are specified minimum purchase requirements under the Lonza Agreement, and under specified circumstances, termination fees may be payable upon termination of the Lonza Agreement by the Company.

AMAG entered into the Ypsomed Agreement on December 20, 2018, and upon the Company and AMAG entering into the Termination Agreement, the Ypsomed Agreement was assigned to Company. The initial term of the Ypsomed Agreement is through December 31, 2025, with automatic renewal for successive one-year periods unless either party terminates the Ypsomed Agreement by ten months' written notice prior to the expiration of the Ypsomed Agreement or any automatic renewal period. The Ypsomed Agreement may be terminated if the other party materially breaches any provisions of the Ypsomed Agreement and such breach is not cured within the period outlined in the Ypsomed Agreement, by the Company if the Company is required to withdraw the defined product from the market, or by either party, if there is a change of control of the other party or the other party becomes insolvent, is dissolved, files a petition in bankruptcy or takes similar action. There are specified minimum purchase requirements under the Ypsomed Agreement, and under specified circumstances, termination fees may be payable upon termination of the Lonza Agreement by the Company.

As part of the Termination Agreement, the Company assumed certain supply agreements with manufacturers and suppliers, including the Catalent Agreement, Lonza Agreement and Ypsomed Agreement. The Company is required to make certain payments for the manufacture and supply of Vyleesi. The following table summarizes the contractual obligations under the Catalent Agreement, Lonza Agreement and Ypsomed Agreement at July 24, 2020:

	Total	Less than 1 Year	1 - 3 Years	4 - 5 Years
Inventory purchase commitments	$ 24,319,542	$ 5,189,542	$ 17,158,000	$ 1,972,000

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, 2020, 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, 2020. 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, 2020, our internal control over financial reporting is effective based on those criteria.

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 25, 2020.

NAME	AGE	POSITION WITH PALATIN
Carl Spana, Ph.D.	58	Chief Executive Officer, President and a Director
John K.A. Prendergast, Ph.D. (3)	66	Director, Chairman of the Board of Directors
Robert K. deVeer, Jr. (1) (2)	74	Director
J. Stanley Hull (1) (2)	68	Director
Alan W. Dunton, M.D. (1) (2)	66	Director
Angela Rossetti (1) (3)	67	Director
Arlene M. Morris (2) (3)	68	Director
Anthony M. Manning, Ph.D. (3)	58	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. 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 scientific expertise, leadership experience, business judgment and industry knowledge. As a senior executive of Palatin for over twenty 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 lead director of Heat Biologics, Inc., a publicly traded clinical stage immunotherapy company, and a director and non-executive chairman 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.

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 companies Recce Pharmaceuticals Ltd (ASX: RCE), Regeneus Ltd (ASX: RGS), CorMedix Inc. (NYSE: CRMD) and Oragenics, Inc. (NYSE: OGEN). 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, regulatory 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. Ms. Rossetti consults with pharmaceutical companies, including consultation on rare disease indications and pharmaceutical utilization in low- and middle-income markets. 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 Unum Therapeutics Inc., a publicly traded solid tumor cancer therapy company, and was a director of Neovacs SA, a publicly traded French company, 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, 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, and since 2018 chief scientific officer, at Momenta Pharmaceuticals, Inc., a publicly traded biopharmaceutical company developing innovative therapeutics for rare immune-related diseases. 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 Inflammation, Autoimmunity and Transplantation Research at 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 2020, the board met six times, the audit committee met four times, the compensation committee met two 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 25, 2020.

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, including the Chairman or non-management directors as a group, 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, together with our chief financial officer and chief operating officer, is responsible for leading our day-to-day performance and operations. 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.	58	Chief Executive Officer, President and Director
Stephen T. Wills, MST, CPA	63	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, currently serves as the Chief Financial Officer (since 1997), Chief Operating Officer (since 2011), Treasurer and Secretary of Palatin. Mr. Wills has served on the board of directors of MediWound Ltd. (Nasdaq: MDWD), a biopharmaceutical company focused on treatment in the fields of severe burns, chronic and other hard to heal wounds, since April 2017, and as Chairman since January 2018, and also has served on the board of directors of Gamida Cell Ltd. (Nasdaq: GMDA), a leading cellular and immune therapeutics company, since March 2019 (audit and finance committee member), and of Amryt Pharma, a biopharmaceutical company focused on developing and delivering treatments to help improve the lives of patients with rare and orphan diseases, since September 2019 (chairman of audit committee and member of the finance committee). Mr. Wills also serves on the board of trustees and executive committee of The Hun School of Princeton, a college preparatory day and boarding school, since 2013, and as its Chairman since June 2018. Mr. Wills served on the board of directors of Caliper Corporation, a psychological assessment and talent development company, since March 2016, and as Chairman from December 2016 to December 2019, when Caliper was acquired by PSI. Mr. Wills served as Executive Chairman and Interim Principal Executive Officer of Derma Sciences, Inc., a provider of advanced wound care products, from December 2015 to February 2017, when Derma Sciences was acquired by Integra Lifesciences (Nasdaq: IART). Previously, Mr. Wills served on the board of directors of Derma Sciences as the lead director and chairman of the audit committee from June 2000 to December 2015. Mr. Wills served as the Chief Financial Officer of Derma Sciences from 1997 to 2000. Mr. Wills served as the President and Chief Operating Officer of Wills, Owens & Baker, P.C., a public accounting firm, from 1991 to 2000. Mr. Wills, a certified public accountant, earned his Bachelor of Science in accounting from West Chester University, and a Master of Science 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 2020.

Item 11. Executive Compensation.

Fiscal 2020 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 2020 and fiscal 2019. 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.,	***2020***	600,000	712,443	712,559	252,000	15,615	2,292,617
Chief Executive Officer and President	***2019***	505,400	616,668	632,225	506,000	14,118	2,274,411
Stephen T. Wills, MST, CPA, Chief Financial Officer,	***2020***	550,000	613,814	613,805	231,000	16,207	2,024,826
Chief Operating Officer and Executive Vice President	***2019***	461,700	527,826	542,151	462,000	14,085	2,007,762

(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. The aggregate grant date fair value of the performance-based stock options and performance-based restricted stock units granted in fiscal 2020, assuming that the highest level of performance would be achieved, was as follows: for Dr. Spana, $337,500 for performance-based stock options and $337,500 for performance-based restricted stock units; and for Mr. Wills, $290,750 for performance-based stock options and $290,750 for performance-based restricted stock units. The aggregate grant date fair value of the performance-based restricted stock units granted in fiscal 2019, assuming that the highest level of performance would be achieved, was $300,428 for Dr. Spana and $257,146 for Mr. Wills. There were no performance-based stock options granted in fiscal 2019. 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) Annual incentive amounts.

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

Base Salary

The salary for each named executive officer is based, among other factors, upon job responsibilities, level of experience, individual performance, comparisons to the salaries of executives in similar positions obtained from market surveys, and internal comparisons. The compensation committee considers changes in the base salaries of our named executive officers annually. In fiscal 2020, the compensation committee approved increases in base salaries to $600,000 for Dr. Spana and $550,000 for Mr. Wills in connection with entering into new employment agreements with each officer.

Annual Incentive Program

We provide annual incentive opportunities to our named executive officers to promote the achievement of annual performance objectives. Each year, the compensation committee establishes the target annual incentive opportunity for each named executive officer, which is based on a percentage of his base salary. For fiscal 2020, the target annual incentive opportunity for each named executive officer equaled 60% of his annual base salary, up from 50% of base salary for fiscal 2019.

The 2020 annual incentive bonus for the named executive officers was determined based on corporate performance and individual achievements and performance, as warranted. 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. The corporate objectives are established so that target attainment is not assured. Instead, our executives are required to demonstrate significant effort, dedication, and achievement to attain payment for performance at target or above.

The following table briefly describes each category of corporate objectives, the relative weighting of each objective, and the related achievement level:

Corporate Objectives Related to:	Weight	Achievement Level	Discretionary Adjustments*	Total Weighted Achievement
Vyleesi (bremelanotide) FSD Program	20%	0%	0%	0%
Anti-Inflammatory Programs	15%	0%	0%	0%
Ocular Programs	45%	77%	15%	40%
Other Corporate	20%	100%	50%	30%
Total Payout				70%

*Discretionary adjustments for ocular programs were primarily related to program advances for PL9643 for dry eye disease, including management of clinical trial enrollment during the COVID-19 pandemic; discretionary adjustments for other corporate were primarily related to management of AMAG's announced divestiture of Vyleesi and management of corporate operations in the light of the COVID-19 pandemic.

For fiscal 2020, the compensation committee determined that our named executive officers achieved 70% of their target objectives. As a result, each named executive officer received a payout under the 2020 annual incentive program equal to 70% of his target annual incentive opportunity, or $252,000 for Dr. Spana and $231,000 for Mr. Wills (subject to rounding conventions).

Long-Term Incentive Program

The total direct compensation levels for our named executive officers are heavily weighted to long-term incentive opportunities. This structure is intended to align executives' interests with those of our stockholders, enhance our retention incentives and focus our executives on delivering sustainable performance over the longer-term.

The design of this program has evolved over the past several years to reflect core performance metrics and an incentive structure the compensation committee believes is necessary to drive our long-term success and that reflects feedback received from investors during our stockholder engagement process.

Each year, the compensation committee establishes the target long-term incentive opportunity for each named executive officer, which is based on a percentage of his base salary. For fiscal 2020, the target long-term incentive opportunity for each named executive officer equaled 250% of base salary for Dr. Spana and 235% of base salary for Mr. Wills.

On June 24, 2019, as part of our 2020 long-term incentive program, we granted 236,000 time-based restricted stock units and 236,000 performance-based restricted stock units to Dr. Spana, and 202,000 time-based restricted stock units and 202,000 performance-based restricted stock units to Mr. Wills. The time-based restricted stock units vest as to 25% of the number of shares granted at each anniversary of the date of grant. The performance-based restricted stock units vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials and licensing of Vyleesi in additional countries or regions.

On June 24, 2019, we also granted 744,000 stock options to Dr. Spana and 638,000 stock options to Mr. Wills, which vest as to 25% of the number of shares granted on each anniversary of the date of grant. The options have an exercise price of $1.34, the fair market value of the common stock on the business day immediately preceding the date of grant, and they expire on June 24, 2029.

On June 16, 2020, as part of our 2021 long-term incentive program, we granted 646,500 time-based restricted stock units and 646,500 performance-based restricted stock units to Dr. Spana, and 557,000 time-based restricted stock units and 557,000 performance-based restricted stock units to Mr. Wills. The time-based restricted stock units vest as to 25% of the number of shares granted at each anniversary of the date of grant. The performance-based restricted stock units vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials, and licensing of Vyleesi in additional countries or regions.

On June 16, 2020, we also granted 1,071,500 time-based options and 1,071,500 performance-based options to Dr. Spana, and 923,000 time-based options and 923,000 performance-based options to Mr. Wills, a portion of which were contingent on increasing the shares reserved for grant under the 2011 Stock Incentive Plan, which was approved by the stockholders at a meeting on June 25, 2020. The time-based options vest as to 25% of the number of shares granted at each anniversary of the date of grant. The performance-based options vest on performance criteria relating to advancement of MC1r programs, including initiation of clinical trials, and licensing of Vyleesi in additional countries or regions. The options have an exercise price of $0.58, the fair market value of the common stock on the business day immediately preceding the date of grant, and they expire on June 16, 2030.

Employment Agreements

Effective July 1, 2019, we entered into employment agreements with Dr. Spana and Mr. Wills which continue through June 30, 2022 unless terminated earlier. Under these agreements, which replaced substantially similar agreements that expired on June 30, 2019, Dr. Spana is serving as Chief Executive Officer and President at a base salary of $600,000 per year and Mr. Wills is serving as Chief Financial Officer and Chief Operating Officer at a base salary of $550,000 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. 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.

Other Compensation Practices and Policies

At our last annual meeting of stockholders on June 25, 2020, our non-binding stockholder advisory vote to approve the compensation of our named executive officers (commonly known as a "Say-on-Pay" vote) was supported by approximately 60% of the votes cast for or against advisory approval. We continue to evaluate our executive compensation program and solicit input from our largest investors. Following is a summary of our current compensation practices and policies.

- *Retain an Independent Compensation Advisor.* The compensation committee engaged Korn Ferry Hay Group ("Hay Group"), a nationally-recognized global human resources consulting firm, as its independent compensation advisor in May 2019. Hay Group principally provided analysis, advice and recommendations on named executive officer and non-employee director compensation. The compensation committee intends to conduct an independent compensation advisor review at least every other fiscal year, with the most recent review by our independent compensation advisor made for awards in June 2019 for the fiscal year ending June 30, 2020. Our compensation peer group for awards made in June 2019 is as follows, which was designed to reflect the industry and sector in which Palatin competes, as well as companies comparable to Palatin in terms of company life cycle, phase of development of potential products, market capitalization and talent market:

  AcelRx Pharmaceuticals, Inc.
  Ardelyx, Inc.
  ArQule, Inc.
  Calithera Biosciences, Inc.
  Savara Inc.
  ChemoCentryx, Inc.
  Cytokinetics, Inc.
  Sutro Biopharma, Inc.
  Geron Corporation
  ImmunoGen, Inc.
  Verastem, Inc.
  La Jolla Pharmaceutical
  MEI Pharma, Inc.
  Protagonist Therapeutics, Inc.
  Rigel Pharmaceuticals, Inc.
  Savara Inc.
  Stemline Therapeutics, Inc.
  Syndax Pharmaceuticals, Inc.
  Verastem, Inc.

  We anticipate engaging an independent compensation advisor for a review for awards to be made in June 2021 for the fiscal year ending June 30, 2022, including utilization of a compensation peer group.

- *Compensation at Risk.* Our executive compensation program is designed so that a significant portion of compensation is "at risk" based on our performance, as well as short-term cash and long-term equity incentives to align the interests of our executive officers and stockholders. Long-term equity incentives will be no less than base salaries, with at least half of long-term equity incentives being performance-based.

- *Use a Pay-for-Performance Philosophy.* The compensation committee employs a mixture of compensation elements designed to balance short-term goals with longer-term performance. Our executive compensation program includes these principal elements:

  - ❑ Base salary, which targets the comparable position median salary for our peer group;

  - ❑ An annual incentive compensation opportunity, with a target bonus payout, effective for fiscal 2020, of no less than 60% of base salary, depending on performance; and,

  - ❑ A long-term incentive program consisting of stock option and restricted stock unit awards. In fiscal 2020, approximately 50% of all long-term incentive awards were allocated to time-based stock options and performance-based restricted share units, with performance-based restricted share units comprising 50% of issued restricted share units.

- *Maintain a Stock Ownership Policy.* We have adopted a stock ownership policy that requires our named executive officers, as well as our board members, to maintain a minimum ownership level of our common stock. As of June 30, 2020, the most recent "Determination Date" under the stock ownership policy, all current named executive officers and board members meet the target ownership levels of shares with a value equal to at least five times the annual base salary of named executive officers and at least two times the annual retainer for board members. Our stock ownership policy is on our website at www.palatin.com/about/corporate-governance/. In addition, certain time-based and performance-based restricted stock unit awards contain deferred delivery provisions providing for delivery of the common stock after the grantee's separation from service or a defined changed in control.

- *Maintain a Clawback Policy*. We have adopted a clawback policy allowing Palatin to recover related compensation should the board determine that compensation paid to named executive officers resulted from material noncompliance with financial reporting requirements under federal securities law. Our clawback policy is on our website at www.palatin.com/about/corporate-governance/.

- *Maintain an Independent Compensation Committee.* The compensation committee consists entirely of independent directors.

- *Annual Executive Compensation Review.* The compensation committee conducts an annual review and approval of our compensation strategy, utilizing an independent compensation advisor at least every other year. This review, including a peer group review, is intended to ensure that our compensation programs appropriately reward corporate growth without encouraging excessive or inappropriate risk-taking.

- *"Double Trigger" Feature for Acceleration of CEO and CFO/COO Equity Awards.* Under employment agreements with our named executive officers, outstanding equity awards granted to our named executive officers provide that, upon a change in control of Palatin, the vesting of such awards will accelerate only in the event of a subsequent involuntary termination of employment (a "double-trigger" provision).

- *No Excise Tax Gross-Ups.* Prior to July 1, 2019, our employment agreements for the named executive officers provided that they were entitled to a tax gross-up for any golden parachute excise tax imposed on payments received in connection with a change in control. Most investors disfavor this type of tax gross-up benefit. In response to stockholder feedback, effective with new employment agreements for our named executive officers commencing July 1, 2019, we removed all golden parachute excise tax gross-up provisions. As a result, the Company no longer provides tax gross-ups for named executive officers or any other employees in the event they are subject to golden parachute excise taxes on payments received in connection with a change in control.

- *No Stock Option Re-pricing.* Our 2011 Stock Incentive Plan does not permit options to purchase shares of our common stock to be repriced to a lower exercise or strike price without the approval of our stockholders.

- *No Dividends or Dividend Equivalents Payable on Unvested or Undelivered Equity Awards.* Under our restricted share unit agreements, we do not pay dividends or dividend equivalents on unvested RSU awards or vested RSU awards subject to delayed delivery.

- *No Executive Retirement Plans.* We do not offer pension arrangements or retirement plans or arrangements to our executive officers that are different from or in addition to those offered to our other employees.

- *No Special Welfare or Health Benefits.* Our executive officers participate in broad-based Company-sponsored health and welfare benefit programs on the same basis as our other full-time, salaried employees.

Outstanding Equity Awards at 2020 Fiscal Year-End

The following table summarizes all of the outstanding equity-based awards granted to our named executive officers as of June 30, 2020, 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	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	300,000	-	-	1.08	06/11/25				
	09/07/16	354,500	77,500	-	0.68	09/07/26				
	06/20/17	703,500	234,500	-	0.37	06/20/27				
	12/12/17	312,500	312,500	-	0.85	12/12/27				
	12/12/17	500,000	-	125,000	0.85	12/12/27				
	06/26/18	266,500	266,500	-	1.00	06/26/28				
	06/24/19	186,000	558,000	-	1.34	06/24/29				
	06/16/20	-	1,071,500	-	0.58	06/16/30				
	06/16/20	-	-	1,071,500	0.58	06/16/30				
	12/12/17						312,500	159,375	125,000	63,750
	06/24/19						177,000	90,270	185,850	94,784
	06/16/20						646,500	329,715	646,500	329,715
	Total Stock Awards						1,136,000	579,360	957,350	488,249
Stephen T. Wills	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	270,000	-	-	1.08	06/11/25				
	09/07/16	324,750	71,250	-	0.68	09/07/26				
	06/20/17	644,250	214,750	-	0.37	06/20/27				
	12/12/17	287,500	287,500	-	0.85	12/12/27				
	12/12/17	372,500	-	95,000	0.85	12/12/27				
	06/26/18	227,000	227,000	-	1.00	06/26/18				
	06/24/19	159,500	478,500	-	1.34	06/24/29				
	06/16/20	-	923,000	-	0.58	06/16/30				
	06/16/20	-	-	923,000	0.58	06/16/30				
	12/12/17						287,500	146,625	95,000	48,450
	06/24/19						151,500	77,265	159,075	81,128
	06/16/20						557,000	284,070	557,000	284,070
	Total Stock Awards						996,000	507,960	811,075	413,648

(1) Stock option vesting schedules: all options granted on or before September 6, 2016 have fully vested. Options granted after September 6, 2016 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 June 16, 2020, which vest according to the terms of the grant described above, and December 12, 2017, which vested as to thirty percent on June 26, 2018, upon ratification by the Board of the compensation committee’s determination that the FDA had accepted for filing an NDA for Vyleesi for HSDD, and fifty percent on June 24, 2019, upon the compensation committee’s determination that FDA had approved the NDA for Vyleesi for HSDD. The remaining 20% will vest, if at all, during the performance period ending December 31, 2020 upon entry into one or more licensing agreements for the commercialization of Vyleesi in selected countries, which is considered a performance condition or upon achievement of a closing price for Palatin common stock equal to or greater than $1.50 per share for 20 consecutive trading days, which is considered a market condition, provided that in no event will the aggregate granted exceed the number of performance-based stock units awarded to Dr. Spana and Mr. Wills.

(2) Time-based stock award vesting schedule: restricted stock units granted on December 12, 2017, as to 625,000 shares for Dr. Spana and 575,000 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 June 24, 2019 as to 236,000 shares for Dr. Spana and 202,000 shares for Mr. Wills and restricted stock units granted on June 16, 2020 as to 646,500 shares for Dr. Spana and 557,000 shares for Mr. Wills, which vest in equal amounts over a four year period, provided that the named executive officer remains an employee. Both time-based and performance-based restricted stock unit awards prior to fiscal 2019 contain deferred delivery provisions providing for delivery of the common stock after the grantee’s separation from service or a defined change 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 $0.51, the closing market price of our common stock on June 30, 2020, 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, 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 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 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% 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 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. 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. Pursuant to the employment agreements, options and restricted stock units granted under the 2011 Stock Incentive Plan vest upon termination of the employee within twelve months following 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 2020, 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	57,400	57,400	212,300
Robert K. deVeer, Jr.	66,250	42,300	42,400	150,950
J. Stanley Hull	57,500	42,300	42,400	142,200
Alan W. Dunton, M.D.	66,250	42,300	42,400	150,950
Angela Rossetti	53,750	42,300	42,400	138,450
Arlene Morris	53,750	42,300	42,400	138,450
Anthony Manning, Ph.D.	48,750	42,300	42,400	133,450

(1) The aggregate number of shares underlying option awards and stock awards outstanding at June 30, 2020 for each director was:

	Option awards	Stock awards
Dr. Prendergast	808,250	259,000
Mr. deVeer	365,500	153,000
Mr. Hull	362,000	153,000
Dr. Dunton	314,000	143,000
Ms. Rossetti	266,500	133,000
Ms. Morris	221,500	123,000
Dr. Manning	149,000	115,000

(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 16, 2020 for our current fiscal year ending June 30, 2021.

Our director compensation program is designed to enhance our ability to attract and retain highly qualified directors and to align their interests with the long-term interests of our stockholders. The program includes an equity component, which is designed to align the interests of non-employee directors and stockholders, and a cash component, which is designed to compensate non-employee directors for their service on the board. Directors who are employees of the Company receive no additional compensation for their service on the board.

The compensation committee annually reviews compensation paid to our non-employee directors and makes recommendations for adjustments, as appropriate, to the full board. As part of this annual review, the compensation committee considers the significant time commitment and skill level required by each non-employee director in serving on the board and its various committees. The compensation committee seeks to maintain a market competitive director compensation program and, with the assistance of its independent compensation consultant, Hay Group, benchmarks our director compensation program against the peer group we use to evaluate our executive compensation program.

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 16, 2020, the Chairman of the board received 99,000 restricted stock units which vest on June 16, 2021 and an option to purchase 172,000 shares of common stock, and each other serving non-employee director received 73,000 restricted stock units which vest on June 16, 2021 and an option to purchase 127,000 shares of common stock. All of the options have an exercise price of $0.58 per share, the closing price of our common stock on the business day immediately preceding the date of grant, vest in twelve monthly installments beginning July 31, 2020, expire ten years from the date of grant and provide for accelerated vesting in the event of involuntary 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 24, 2019, the Chairman of the board received 84,000 restricted stock units which vested on June 24, 2020, and an option to purchase 70,000 shares of common stock, and each other serving non-employee director received 32,000 restricted stock units which vested on June 24, 2020, and an option to purchase 52,000 shares of common stock. All of the options have an exercise price of $1.34 per share, the closing price of our common stock on the business day immediately preceding the date of grant, vested in twelve monthly installments beginning on July 31, 2019, 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 2020 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 $17,500, the chairperson of the compensation committee received an additional annual retainer of $17,500 and the chairperson of the corporate governance committee received an additional annual retainer of $10,000. 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, 2021, Dr. Prendergast serves as Chairman of the board and will received an annual retainer of $87,500, payable quarterly. Other non-employee directors will receive an annual base retainer of $40,000, payable on a quarterly basis. The chairperson of the audit committee will receive an additional annual retainer of $17,500, the chairperson of the compensation committee will receive an additional annual retainer of $17,500 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.

The board also formed a program development committee, charged with reviewing new product opportunities and product development strategy. The chairperson of the program development committee receives $3,500 per day of service, and members of the committee receive $2,500 per day of service.

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, 2020:

Equity Compensation Plan Information
as of June 30, 2020

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	32,592,020(1)	$ 0.76(2)	5,552,149
Equity compensation plans not approved by security holders	25,000(3)	$ 0.70	-
Total	32,617,020		5,552,149

(1) Includes 19,888,450 options and 12,965,570restricted stock units granted under our 2011 Stock Incentive Plan and 14,000 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 12,689,570 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 16, 2024, 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 24, 2020, 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 24, 2020. 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 16 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 24, 2020, on which date 229,855,417 shares of common stock and 4,030 shares of Series A preferred stock, convertible into 66,059 shares of common stock, were outstanding.

Under our Insider Trading and Securities Law Compliance Policy directors and officers may not engage in hedging, monetization or pledging transactions of our securities. None of the shares of our management and directors shown on the table below are pledged.

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.	7,187,368(1)	3.0%	*
Common	Stephen T. Wills	6,380,047(2)	2.7%	*
Common	John K.A. Prendergast, Ph.D.	1,202,349(3)	*	*
Common	Robert K. deVeer, Jr.	697,472(4)	*	*
Common	J. Stanley Hull	650,132(5)	*	*
Common	Alan W. Dunton, M.D.	610,684(6)	*	*
Common	Angela Rossetti	535,332(7)	*	*
Common	Arlene M. Morris	477,332(8)	*	*
Common	Anthony M. Manning, Ph.D.	256,332(9)	*	*
	All current directors and executive officers as a group (nine persons)	17,997,048(10)	7.4%	1.4%

*Less than one percent.

(1) Includes 3,600,500 shares of common stock underlying outstanding options and 2,703,500 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 providing for delivery after the grantee's separation from service or a defined change 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 3,141,750 shares of common stock underlying outstanding options and 2,376,000 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 providing for delivery after the grantee's separation from service or a defined change 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 667,582 shares of common stock underlying outstanding options and 140,000 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 providing for delivery after the grantee's separation from service or a defined change 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 386,332 shares of common stock underlying outstanding options and 70,000 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 providing for delivery after the grantee's separation from service or a defined change 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 386,332 shares of common stock underlying outstanding options and 70,000 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 providing for delivery after the grantee's separation from service or a defined change 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 346,332 shares of common stock underlying outstanding options and 60,000 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 providing for delivery after the grantee's separation from service or a defined change 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 298,832 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 providing for delivery after the grantee's separation from service or a defined change 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 253,832 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 providing for delivery after the grantee's separation from service or a defined change 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 159,332 shares of common stock underlying outstanding options and 10,000 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 providing for delivery after the grantee's separation from service or a defined change 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 14,760,324 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 New Canaan, CT 06840	500	12.4%*
Series A Preferred	Jonathan E. Rothschild 300 Mercer St., #28F New York, NY 10003	500	12.4%*
Series A Preferred	Arthur J. Nagle 19 Garden Avenue Bronxville, NY 10708	250	6.2%*
Series A Preferred	Thomas P. and Mary E. Heiser, JTWROS 10 Ridge Road Hopkinton, MA 01748	250	6.2%*
Series A Preferred	Carl F. Schwartz 31 West 87th St. New York, NY 10016	250	6.2%*
Series A Preferred	Michael J. Wrubel 3650 N. 36 Avenue, #39 Hollywood, FL 33021	250	6.2%*
Series A Preferred	Myron M. Teitelbaum, M.D. 175 Burton Lane Lawrence, NY 11559	250	6.2%*
Series A Preferred	Laura Gold Galleries Ltd. Profit Sharing Trust Park South Gallery at Carnegie Hall 154 West 57th Street, Suite 114 New York, NY 10019	250	6.2%*
Series A Preferred	Laura Gold 180 W. 58th Street New York, NY 10019	250	6.2%*
Series A Preferred	Nadji T. Richmond 20 E. Wedgewood Glen The Woodlands, TX 77381	230	5.7%*

*Less than one percent.

(1) Unless otherwise indicated by footnote, all share amounts represent outstanding shares of the class indicated, and all beneficial owners listed have, to our knowledge, sole voting and dispositive power over the shares listed.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The board of directors has determined that all the directors except for Dr. Spana (our Chief Executive Officer and President) are independent directors, as defined in the listing standards of the NYSE American.

As a condition of employment, we require all employees to disclose in writing actual or potential conflicts of interest, including related party transactions. Our code of corporate conduct and ethics, which applies to employees, officers and directors, requires that the audit committee review and approve related party transactions. Since July 1, 2015, there have been no transactions or proposed transactions in which we were or are to be a participant, in which any related person had or will have a direct or indirect material interest.

Item 14. Principal Accounting Fees and Services.

KPMG LLP ("KPMG"), served as our independent registered public accounting firm for fiscal 2020 and fiscal 2019.

Audit Fees. For fiscal 2020, fees for professional services rendered for the audit of our annual consolidated financial statements, review of our consolidated financial statements in our Forms 10-Q, and services provided in connection with comfort letters were $329,000. For fiscal 2019, fees for professional services rendered for the audit of our annual consolidated financial statements, the audit of internal control over financial reporting as of June 30, 2019, review of our consolidated financial statements in our Forms 10-Q, and services provided in connection with regulatory filings and comfort letters were $504,000.

Audit-Related Fees. For fiscal 2020 and fiscal 2019, KPMG did not perform or bill us for any audit-related services.

Tax Fees. For fiscal 2020, KPMG billed us $23,600 for professional services rendered for tax compliance services. For fiscal 2019, KPMG billed us a total of $37,000 for professional services rendered for tax compliance and consulting services.

All Other Fees. KPMG did not perform or bill us for any services other than those described above for fiscal 2020 and fiscal 2019.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors. Consistent with SEC policies regarding auditor independence, the audit committee has responsibility for appointing, setting compensation for and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the audit committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm.

The audit committee pre-approves fees for each category of service. The fees are budgeted and the audit committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the audit committee requires specific pre-approval before engaging the independent registered public accounting firm.

The audit committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the audit committee at its next scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of the report:

1. Financial statements: The following consolidated financial statements are filed as a part of this report under Item 8 – Financial Statements and Supplementary Data:

   — Report of Independent Registered Public Accounting Firm

   — Consolidated Balance Sheets

   — Consolidated Statements of Operations

   — Consolidated Statements of Comprehensive (Loss) Income

   — Consolidated Statements of Stockholders' Equity (Deficiency)

   — Consolidated Statements of Cash Flows

   — Notes to Consolidated Financial Statements

2. Financial statement schedules: None.

3. List of Exhibits

   The following exhibits are incorporated by reference or filed as part of this report:

Exhibit Number	Description	Filed Herewith	Form	Filing Date	SEC File No.
1.1	Equity Distribution Agreement, dated April 20, 2018, by and between Palatin Technologies, Inc. and Canaccord Genuity LLC		8-K	April 20, 2018	001-15543
1.2	Equity Distribution Agreement, dated June 21, 2019, by and between Palatin Technologies, Inc. and Canaccord Genuity LLC		8-K	June 21, 2019	001-15543
3.1	Restated Certificate of Incorporation of Palatin Technologies, Inc., as amended.		10-K	September 27, 2013	001-15543
3.2	Bylaws of Palatin Technologies, Inc.		10-Q	February 8, 2008	001-15543
4.1	Form of Series A 2012 Warrant.		8-K	July 6, 2012	001-15543
4.2	Form of Series B 2012 Warrant.		8-K	July 6, 2012	001-15543
4.3	Form of Series C 2014 Common Stock Purchase Warrant.		8-K	December 30, 2014	001-15543
4.4	Form of Series D 2014 Common Stock Purchase Warrant.		8-K	December 30, 2014	001-15543
4.5	Form of Series E 2015 Common Stock Purchase Warrant.		8-K	July 7, 2015	001-15543
4.6	Form of Series F 2015 Common Stock Purchase Warrant.		8-K	July 7, 2015	001-15543
4.7	Form of Series G 2015 Common Stock Purchase Warrant.		8-K	July 7, 2015	001-15543
4.8	Form of Series H 2016 Common Stock Purchase Warrant.		8-K	August 2, 2016	001-15543
4.9	Form of Series I 2016 Common Stock Purchase Warrant.		8-K	August 2, 2016	001-15543
4.10	Form of Series J 2016 Common Stock Purchase Warrant.		8-K	December 1, 2016	001-15543
4.11	Form of warrant issued to PSL Business Development Consulting and SARL Avisius in connection with a contract for financial advisory services.		10-Q	February 10, 2017	001-15543

4.12	Description of Securities	10-K	September 12, 2019	001-15543
10.1†	1996 Stock Option Plan, as amended.	10-K	September 28, 2009	001-15543
10.2†	Form of Option Certificate (Incentive Option) Under the 2005 Stock Plan.	8-K	September 21, 2011	001-15543
10.3†	Form of Incentive Stock Option Under the 2005 Stock Plan.	8-K	September 21, 2011	001-15543
10.4†	Form of Opinion Certificate (Non-Qualified Opinion) Under the 2005 Stock Plan.	8-K	September 21, 2011	001-15543
10.5†	Form of Non-Qualified Stock Option Agreement Under the 2005 Stock Plan.	8-K	September 21, 2011	001-15543
10.6†	2007 Change in Control Severance Plan.	10-Q	February 8, 2008	001-15543
10.7†	2005 Stock Plan, as amended.	10-Q	May 15, 2009	001-15543
10.8†	Form of Executive Officer Option Certificate.	10-Q	May 14, 2008	001-15543
10.9†	Form of Amended Restricted Stock Unit Agreement.	10-Q	May 14, 2008	001-15543
10.10†	Form of Amended Option Certificate (Incentive Option) Under the 2005 Stock Plan.	10-Q	May 14, 2008	001-15543
10.11†	2011 Stock Incentive Plan, as amended.	8-K	June 27, 2018	001-15543
10.12†	Form of Restricted Share Unit Agreement Under the 2011 Stock Incentive Plan.	10-Q	May 13, 2011	001-15543
10.13†	Form of Nonqualified Stock Option Agreement under the 2011 Stock Incentive Plan.	10-Q	May 13, 2011	001-15543
10.14†	Form of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan.	10-Q	May 13, 2011	001-15543
10.15†	Form of Restricted Share Unit Agreement under the 2011 Stock Incentive Plan.	8-K	December 11, 2015	001-15543

10.16†	Form of Performance-Based Restricted Share Unit Agreement under the 2011 Stock Incentive Plan.	8-K	December 11, 2015	001-15543
10.17†	Form of Restricted Share Unit Agreement for Non-Employee Directors under the 2011 Stock Incentive Plan.	8-K	December 11, 2015	001-15543
10.18†	Amended form of Restricted Share Unit Agreement under the 2011 Stock Incentive Plan.	10-Q	February 12, 2016	001-15543
10.19†	Amended form of Performance-Based Restricted Share Unit Agreement under the 2011 Stock Incentive Plan.	10-Q	February 12, 2016	001-15543
10.20†	Amended form of Restricted Share Unit Agreement for Non-Employee Directors under the 2011 Stock Incentive Plan.	10-Q	February 12, 2016	001-15543
10.21	Form of Indenture.	S-3	August 17, 2018	333-226905
10.22	Amended and Restated Venture Loan and Security Agreement, dated July 2, 2015, by and between Palatin Technologies, Inc. and Horizon Technology Finance Corporation, Fortress Credit Co LLC, Horizon Credit II LLC and Fortress Credit Opportunities V CLO Limited.	8-K	July 7, 2015	001-15543
10.23††	Commercial Supply Agreement dated June 20, 2016, by and between Catalent Belgium S.A. and Palatin Technologies, Inc.	10-K	September 19, 2016	001-15543
10.24††	Manufacturing Preparation and Services Agreement dated June 20, 2016, by and between Catalent Belgium S.A. and Palatin Technologies, Inc.	10-K	September 19, 2016	001-15543
10.25††	License Agreement, dated January 8, 2017, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc.	10-Q	February 10, 2017	001-15543
10.26††	License Agreement, dated September 6, 2017, by and between Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. and Palatin Technologies, Inc.	10-Q	November 13, 2017	001-15543
10.27†	Employment Agreement, effective as of July 1, 2019, between Carl Spana and Palatin Technologies, Inc.	8-K	June 26, 2019	001-15543

10.28†	Employment Agreement, effective as of July 1, 2019, between Stephen T. Wills and Palatin Technologies, Inc.		8-K	June 26, 2019	001-15543
10.29	Termination Agreement between Palatin Technologies, Inc. And AMAG Pharmaceuticals, Inc., dated July 24, 2020.		8-K	July 27, 2020	001-15543
10.30†††	Manufacturing Services Agreement, dated as of June 1, 2019, by and between Palatin Technologies, Inc. (as assignee from AMAG Pharmaceuticals, Inc.) and Lonza Ltd.	X			
10.31†††	Supply Agreement, dated as of December 20, 2018, by and between Palatin Technologies, Inc. (as assignee from AMAG Pharmaceuticals, Inc.) and Ypsomed AG.	X			
21	Subsidiary of Palatin Technologies, Inc.	X			
23	Consent of KPMG LLP.	X			
31.1	Certification of Chief Executive Officer.	X			
31.2	Certification of Chief Financial Officer.	X			
32.1	Certification of principal executive officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2	Certification of principal financial officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	XBRL Instance Document.	X			
101.SCH	XBRL Taxonomy Extension Schema Document.	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X			

† Management contract or compensatory plan or arrangement.
†† Confidential treatment granted as to certain portions of the exhibit, which portions are omitted and filed separately with the SEC.
††† Portions of the exhibit are omitted pursuant to Regulation S-K Item 601(b)(10). Palatin agrees to furnish to the U.S. Securities and Exchange Commission a copy of any omitted schedule and/or exhibit upon request. The confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PALATIN TECHNOLOGIES, INC.

By: /s/ Carl Spana

Carl Spana, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: September 25, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Carl Spana Carl Spana	President, Chief Executive Officer and Director (principal executive officer)	September 25, 2020
/s/ Stephen T. Wills Stephen T. Wills	Executive Vice President, Chief Financial Officer and Chief Operating Officer (principal financial and accounting officer)	September 25, 2020
/s/ John K. A. Prendergast John K. A. Prendergast	Chairman and Director	September 25, 2020
/s/ Robert K. deVeer, Jr, Robert K. deVeer, Jr.	Director	September 25, 2020
/s/ J. Stanley Hull J. Stanley Hull	Director	September 25, 2020
/s/ Alan W. Dunton Alan W. Dunton	Director	September 25, 2020
/s/ Angela Rossetti Angela Rossetti	Director	September 25, 2020
/s/ Arlene M. Morris Arlene M. Morris	Director	September 25, 2020
/s/ Anthony M. Manning Anthony M. Manning	Director	September 25, 2020

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

Manufacturing Services Agreement

(the "Agreement")

by and between

Lonza Ltd
Münchensteinerstrasse 38
CH-4002 Basel
Switzerland

- hereinafter "Lonza" -

and

AMAG Pharmaceuticals, Inc.
1100 Winter St, Waltham,
MA 02451

- hereinafter "Customer" –

Effective as of 1 June, 2018 (the "Effective Date")

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Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of product;

WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;

WHEREAS, Lonza and Palatin Technologies, Inc. ("Palatin") entered into a Service Agreement dated as of November 11, 2015, as amended on January 19, 2016 and November 11, 2017 (the "Palatin Service Agreement");

WHEREAS, pursuant to a License Agreement entered into as of January 8, 2017, by and between Customer and Palatin (the "Palatin License Agreement"), Palatin was obligated to assign to Customer agreements that relate to the manufacture or supply of the Product, as defined herein, including specifically the Palatin Service Agreement;

WHEREAS, on December 27, 2017, Palatin assigned to Customer the Palatin Service Agreement;

WHEREAS, Customer wishes to engage Lonza for Services relating to the manufacture of the Product as described in this Agreement; and

WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:

1Definitions and Interpretation

"Affiliate"	means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the power to direct or cause the direction of the general management and policies of the relevant Party.
"Agreement"	means this agreement incorporating all Appendices, as amended from time to time by written agreement of the Parties.
"Applicable Laws"	means all relevant federal, state and local laws, statutes, rules, and regulations in the Territory which are applicable to a Party's activities hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority and all applicable cGMP together with amendments thereto.

“Approval”	means the first marketing approval by the FDA or EMA of Product from the Facility for commercial supply.
“Background Intellectual Property”	means any Intellectual Property either (i) owned or controlled by a Party prior to the Effective Date or (ii) developed or acquired by a Party (a) independently from the performance of the Services hereunder during the Term of this Agreement and (b) that does not claim or otherwise expressly incorporate the other Party’s Intellectual Property.
“Batch”	means the Product derived from a single run of the Manufacturing Process, yielding approximately [***] of Product.
"Batch Price"	means the Price of each Batch.
“Binding Forecast”	has the meaning given in Section 6.1.
“Campaign”	means a series of cGMP Batches manufactured consecutively.
“Cancellation Fee”	has the meaning given in Section 6.7.
“Capacity Reservation”	has the meaning given in Section 6.5.
“Certificate of Analysis”	means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specifications and test results.
“cGMP”	means those laws and regulations applicable in the Territory, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC, each as may be amended from time to time. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents.
“cGMP Batches”	means any Batches which are required under the Project Plan to be manufactured in accordance with cGMP.

"Change"	means any change to the Services, Specifications, pricing or Scope of Work incorporated into a written amendment to the Agreement in accordance with clause 15.2 or effected in accordance with the Quality Agreement.
"Change Order"	means a document in the format provided in **Appendix E** provided by Lonza to Customer outlining a proposed adjustment (increase or decrease) to the Price and the reasons for such adjustment, such document to be reviewed and signed by both parties to enable such adjustment to take effect.
"Commencement Date"	means the date of commencement of manufacturing activities for a Campaign or Batch hereunder.
"Confidential Information"	means Customer Information and Lonza Information, as the context requires.
"Customer Indemnitees"	has the meaning given in Section 11.1.
"Customer Information"	means all information that is proprietary to Customer or any Affiliate of Customer and that is maintained in confidence by Customer or any Affiliate of Customer and that is disclosed by Customer or any Affiliate of Customer to Lonza under or in connection with this Agreement, including without limitation, the Manufacturing Process, any and all Customer know-how and trade secrets, and any materials supplied by Customer to Lonza in accordance with this Agreement.
"Delivery Date"	means the delivery date of a Batch as set forth in a Purchase Order and confirmed by Lonza in accordance with Section 6.3.
"Disclosing Party"	has the meaning given in Section 12.1.
"EMA"	means the European Medicines Agency, or any successor agency thereto.
"External Laboratories"	means any Third Party instructed by Lonza, with Customer's prior consent, which is to conduct activities required to complete the Services.
"Facility"	means Lonza's manufacturing facilities in [***] or such other Lonza facility as may be agreed upon by the Parties.
"Failure to Supply"	has the meaning given in Section 7.4.1.

“FDA”	means the United States Food and Drug Administration, or any successor agency thereto.
“Forecast”	has the meaning given in Section 6.1.
“Governmental Authority”	means any Regulatory Authority and any national, multi-national, regional, state or local regulatory agency, department, bureau, or other governmental entity in the Territory.
“Intellectual Property”	means (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered, and (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i) in each case, which exist now or which come to exist in the future, anywhere in the world.
“LOI”	has the meaning given in Section 2.4.
“LOI Batch”	has the meaning given in Section 2.4.
“Lonza Indemnitees”	has the meaning given in Section11.2.
“Lonza Information”	means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including without limitation, any and all Lonza know-how and trade secrets.
“Lonza Manufacturing-related IP”	has the meaning given in Section 9.7.
“Lonza Release”	has the meaning given in Section 7.1.
“Manufacturing Process”	means the production process provided by Customer for the manufacture of Product, as such process may be improved or modified from time to time by agreement of the Parties in writing.
“Master Batch Record”	means the document, proposed by Lonza and approved by Customer, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product.
“Minimum Quantity”	has the meaning given in Section 6.4.

“Minimum Quantity Penalty”	has the meaning given in Section 6.4.
“Necessary Consumables”	has the meaning given in Section 2.8.
“New Customer Intellectual Property”	has the meaning given in Section 9.2.
"New General Application Intellectual Property”	has the meaning given in Section 9.3.
“Party”	means each of Lonza and Customer and, together, the “Parties”.
“Price”	means the price for the Services and Products as set out in Appendix A.
“Process Validation Batch”	means a Batch that is produced with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.
“Product”	means the proprietary molecule identified by Customer as PI-001 (Bremelanotide), to be manufactured using the Manufacturing Process by Lonza for Customer as specified in the Project Plan.
“Project Plan”	means the plan(s) describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time. The initial Project Plan is attached hereto as **Appendix B**.
“Purchase Order”	has the meaning set forth in Section 6.2.
“Quality Agreement”	means the quality agreement, attached hereto as **Appendix C**, setting out the responsibilities of the Parties in relation to quality as required for compliance with the Manufacturing Process, Specifications and cGMP.
“Raw Materials”	means all general ingredients, solvents, amino acids, and other components of the Product required to perform the Manufacturing Process or Services set forth in the bill of materials detailing the same (excluding [***], which is defined as “Specialty Material” herein).
“Receiving Party”	has the meaning given in Section 12.1.
“Specialty Material”	means [***].
"Specialty Material Fee"	means a procurement and handling fee of [***] of the acquisition cost of Specialty Material by

Lonza that is charged to the Customer in accordance with Section 2.9. In the event that Specialty Material will be used less than [***] times, the handling fee for the next purchase of Specialty Materials shall be reduced to [***].

"Regulatory Authority" means the FDA, EMA and any other similar regulatory authorities in the Territory.

"Release for Delivery" has the meaning given in Clause 7.1.

"Services" means all or any part of the services to be performed by Lonza under this Agreement (including, without limitation, process and analytical method transfer, process development, process optimization, validation, clinical and commercial manufacturing, as well as quality control and quality assurance activities), particulars of which are set out in a Project Plan and the Quality Agreement.

"Specifications" means the specifications of the Product as specified in **Appendix D**, which may be amended from time to time in accordance with this Agreement.

"Term" has the meaning given in Section 13.1.

"Territory" means the United States, European Union and such other countries as may be agreed upon by the Parties.

"Third Party" means any party other than Customer, Lonza and their respective Affiliates.

"Up-Front Payment" has the meaning set forth in **Appendix A**.

In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word "including" are to be construed without limitation.

2 Commitments and Performance of Services

2.1 Performance of Services. Lonza shall itself and through its Affiliates, diligently carry out the Services as provided in the Project Plan. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract or delegate any of its rights or obligations under this Agreement to an External Laboratory to perform the Services only with prior written consent from Customer; provided, that any External Laboratories shall be subject to the same obligations and other provisions contained in this Agreement or any applicable Project Plan. In the event that Customer requests

Lonza to outsource certain services to an External Laboratory appointed by Customer, Lonza shall not be responsible for analytical lab services performed by External Laboratories.

2.2 cGMP Batch(es). Lonza will, in accordance with the terms of this Agreement and Quality Agreement, manufacture at the Facility and deliver to Customer, cGMP Batches that comply with the Manufacturing Process, cGMP and the Specifications, together with a Certificate of Analysis and all other documentation as set forth in the Quality Agreement. Prior to commencement of cGMP manufacturing in 2018, Lonza shall review the process assumptions. In the event that there is a material difference in the process assumptions as compared with the process results demonstrated during previous manufacturing campaigns, the Parties shall meet to discuss in good faith to resolve the matter.

2.2.1 Notwithstanding anything herein to the contrary or in the Quality Agreement, except as otherwise agreed to by Customer in writing or as may be required to comply with Applicable Laws (including cGMPs), Lonza shall not amend, change, or supplement any of the following without Customer's prior written consent: (1) the Specifications; (2) the specifications for or the source of Raw Materials or Specialty Materials that have regulatory impact; (3) the equipment and machinery, other than in-kind replacements, used in the manufacture of Product that have a direct impact on the quality of the Product; (4) the test methods used in connection with manufacturing Product that have regulatory impact; or (5) the Manufacturing Process.

2.2.2 In the event that Lonza is required to change any of the foregoing in order to comply with a change in an Applicable Law (including cGMPs) or such change is otherwise agreed to by Customer in writing, Lonza shall: (i) immediately notify Customer of such change and use commercially reasonable efforts to implement such change as soon as reasonably practicable; (ii) be responsible for ensuring that all Product manufactured following such change meets the Specifications; and (iii) provide Customer with all information with respect to the manufacture of the Product in connection with such change needed to amend any regulatory filings maintained with respect to the Product. [***].

2.2.3 In the event that Customer desires to propose a discretionary change (i.e., changes which are not required by cGMPs or other Applicable Laws) under Section 2.2.1 during the Term, the Parties shall discuss such discretionary changes and any manufacturing issues identified by either Party in connection with implementing such change. In all cases, such discretionary changes shall be made in accordance with any change control procedures in the Quality Agreement to the extent applicable. [***].

2.2.4 In the event that Lonza desires to propose a discretionary change (i.e., changes which are not required by cGMPs or other Applicable Laws) under Section 2.2.1 during the Term, the Parties shall discuss such discretionary changes and any manufacturing issues identified by either Party in connection with implementing such change. In all cases, such discretionary changes shall be made in accordance with any change control procedures in the Quality Agreement to the extent applicable. [***].

2.2.5 Lonza acknowledges that any such change(s) under this Section 2.2 shall, in each case, comply with cGMP, this Agreement and the Quality Agreement. Any

such amended Specifications shall be reflected in and attached hereto as an amended and restated **Appendix D**.

2.3 Process Validation Batches. Customer may request Lonza to manufacture and deliver Process Validation Batches as mutually agreed by Parties sufficient to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the necessary regulatory documents. Any and all validation effort shall be additional and outside the scope of this Project Plan. No Validation effort is currently anticipated as part of the current Project Plan.

2.3.1 Upon request of Customer, Lonza and Customer shall further discuss and agree to a process validation plan identifying the validation requirements of the Manufacturing Process. Any and all process validation activities are not considered as part of the Project Plan and are excluded from the Prices within this Agreement. Any such future Process Validation or Process Validation Batches shall be approved by the Customer in advance and shall be paid for by the Customer at a Price to be determined in a separate Project Plan.

2.4 Letter of Intent. The Parties entered into a Letter of Intent dated [***] (the "**LOI**") [***] (the "**LOI** [***]"). In accordance with Sections 6(c) and 11 of the LOI, the terms covenants and conditions of this Agreement govern the supply of the LOI [***] and such LOI [***] is deemed to be Product manufactured by Lonza and supplied to AMAG under this Agreement. In the event of a conflict between this Agreement and the LOI, this Agreement shall control.

2.5 Regulatory Support Activities. Any regulatory support documentation (including, without limitation, documentation related to pre-Approval inspection and provision of any data and information (in English) relating to Lonza's performance under this Agreement) required and agreed to by Customer to support and maintain the Approval of the Product from the Facility shall be performed and supported by Lonza as reasonably requested by Customer. [***]. If required, additional regulatory support activities shall be approved by the Customer in advance, [***] at a price set out in a separate Project Plan.

2.6 Commercial manufacturing and supply. Customer shall purchase Product from Lonza during the Term at the Price outlined in **Attachment A**. Lonza shall manufacture all Product as ordered and accepted per Section 6, under this Agreement at the Facility and pursuant to the terms hereof and the Quality Agreement. Manufacturing of Product may not be relocated from the Facility without Customer's prior written consent.

2.7 Supply of Customer Information. Customer shall supply to Lonza all Customer Information and other information or materials that may be reasonably required by Lonza to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide such Customer Information or other information or materials reasonably required to perform the Services to Lonza.

2.8 Raw Materials. Lonza shall procure all required Raw Materials as well as consumables necessary to perform the Services (the " **Necessary Consumables**"). In order to fulfil its obligations under this Agreement, Lonza may purchase and hold a minimum of [***] extra Batch's requirements of Raw Materials to serve as safety stock.

2.9 Specialty Material and Specialty Material Fee. Specialty Material is not considered part of the Raw Materials and shall be ordered and invoiced separately from Raw Materials. Specialty Material shall be ordered and stocked by Lonza only upon reasonable notice

to and approval by Customer, such notice not to be unreasonably withheld. The Specialty Material Fee is intended compensate Lonza for the procurement and handling of the Specialty Material, any development or validation efforts Lonza performs in order to prepare, use, clean and/or store Specialty Material (including any experimentation to determine the number of times Specialty Material may be reused), and Lonza's preparation, use, cleaning and/or storage of Specialty Material. Lonza shall submit an invoice to Customer, together with sufficient substantiating documentation, for the cost of Specialty Material and the associated Specialty Material Fee. Customer shall pay invoices under this Section in accordance with Section 8.

3 Project Management / Steering Committee

3.1 Project Plan. With respect to the Services to be governed by this Agreement, a Project Plan shall be added by agreement in a writing signed by the Parties and appended to Appendix B. The Project Plan shall include a description of the Services to be provided and such other information as is necessary for performance of the Services. In the event of a conflict between the terms of a Project Plan and this Agreement, the terms of this Agreement will govern unless the terms of the Project Plan expressly override the terms of the Agreement set forth herein.

3.2 Project Management. Each party will appoint a project manager who will be the party responsible for overseeing the Project Plan.

3.3 Steering Committee. Each Party shall name a mutually agreed upon equal number of representatives for the Steering Committee, which shall meet twice per calendar year, or as otherwise mutually agreed by the Parties. In the event that a Steering Committee dispute cannot be resolved, such dispute shall be escalated to a senior executive of each of Customer and Lonza.

The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall also take on the following responsibilities:

3.3.1 discuss and seek resolution of issues around management of the Services;

3.3.2 agree and monitor deadlines and milestones for the Services; and

3.3.3 discuss and recommend any changes to the Services (although such changes will not take effect until they have been incorporated into a written amendment to the Project Plan which has been signed by the Parties).

3.4 Person in Plant. In addition to the inspection and audit rights set forth in Section 4.2 and the Quality Agreement, Customer shall be permitted to have, at no additional cost, [***] at the Facility as reasonably requested by Customer, [***] the Manufacturing Process for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such [***] shall be subject to and agree to abide by confidentiality obligations of this Agreement and Lonza's customary practices and operating procedures regarding persons in plant, and such [***] agrees to comply with all instructions of Lonza's employees at the Facility.

4 Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail except on quality matters where the Quality Agreement shall prevail. Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing.

4.2 Inspections by Regulatory Authorities and audits shall be in accordance with the Quality Agreement.

5 Insurance

5.1 Each Party shall, during the Term and for [***] years after delivery of the last Product manufactured or Services provided under this Agreement, obtain and maintain [***] from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least [***] per claim. Each Party shall provide the respective other Party with a copy of the certificate of such insurance upon reasonable request.

6 Forecasting, Ordering and Cancellation

6.1 Forecast and Binding Forecast. No later than the first (1st) day of each calendar quarter, Customer shall supply Lonza with a written forecast showing Customer's good faith estimated quarterly requirements for Batches for the following [***] period (the "**Forecast**"). No later than [***] following Lonza's receipt of a Forecast, Lonza shall provide written notice to Customer of whether it has (as of the date of receipt of the Forecast) capacity available to manufacture the number of Batches forecasted therein and shall provide Customer with an estimated production schedule showing the estimated Commencement Date and delivery date of each Batch. In the event Customer disputes all or a portion of such production schedule provided by Lonza, the Parties agree to negotiate in good faith the disputed portion(s) of such production schedule. Upon agreement between the Parties regarding the production schedule set forth in the Forecast, the first [***] of such Forecast shall be binding on both Parties (the "**Binding Forecast**"). For the sake of clarity, such Binding Forecast shall include at least the Minimum Quantity as set forth in Section 6.4. If the Binding Forecast exceeds the Capacity Reservation as set forth in Section 6.5, Lonza will use commercially reasonable efforts to include such excess Batch(es) in its production schedule.

6.2 Purchase Order. Customer shall provide Lonza with a binding purchase order in writing (the " **Purchase Order**") a minimum of [***] prior to the scheduled Commencement Date of each Batch consistent with the Binding Forecast under Section 6.1.

6.3 Purchase Order Confirmation. Lonza shall confirm the delivery date as set out in each Purchase Order within [***] business days of receipt from Customer of the relevant Purchase Order (the "**Delivery Date**"). Upon confirmation, each Purchase Order will be regarded by the Parties as a binding commitment by Lonza to manufacture and to deliver to Customer the Batch according to the requirements set out in such Purchase Order. Lonza will make commercially reasonable efforts to effect delivery as close as possible to the Delivery Date set forth in the Purchase Order confirmation, provided that in no event shall actual delivery be greater than [***] before or after such Delivery Date. [***]. Any additional or inconsistent terms or conditions of any Purchase Order, acknowledgement or similar standardized form given or received pursuant to this

Section shall have no effect and such additional or inconsistent terms or conditions are hereby rejected.

6.4 Minimum Quantity. Customer undertakes to purchase from Lonza a minimum of [***] per calendar year during the Term of the Agreement ("**Minimum Quantity**"). For the purposes of this section, a Batch is considered "purchased" as of the Commencement Date in the Purchase Order confirmed by Lonza in accordance with Section 6.3. If Customer fails to purchase the Minimum Quantities in any calendar year, Lonza shall submit an invoice to Customer in January of the next calendar year and Customer shall pay the [***] ("**Minimum Quantity Penalty**"), within [***] after receipt of such invoice.

6.5 Capacity Reservation**.** Lonza shall reserve capacity to manufacture the Minimum Quantity agreed between the Parties plus [***] per applicable calendar year during the Term of the Agreement, starting in 2019 ("**Capacity Reservation**").

6.6 First Commercial Batch. Lonza agrees to manufacture [***]. This commercial [***] will be manufactured in accordance with the Specifications. The Parties agreed upon the pricing of [***] in the Letter of Intent entered into as [***].

6.7 Cancellation Fee. Customer may cancel a Purchase Order upon written notice to Lonza, subject to the payment of a cancellation fee equal to [***] with supplier, of each such Batch cancelled under the Purchase Order (the "**Cancellation Fee**"). Any Up-Front Payment paid by Customer to Lonza in accordance with **Appendix A** shall be deducted from such Cancellation Fee; provided, however, to the extent that such Up-Front Payment was used by Lonza to purchase Raw Materials in reliance on such cancelled Purchase Order, (i) the cost of such Raw Materials, as substantiated by sufficient documentation, shall not be deducted from the Cancellation Fee, and (ii) such Raw Materials shall be used by Lonza in the preparation of a subsequent Batch (and the cost of such Raw Materials shall be deducted from the Batch Price for such subsequent Batch) or otherwise disposed of at Customer's direction. Any Cancellation Fee shall be payable in accordance with Section 8 herein. For the purpose of calculating whether Customer has purchased the Minimum Quantity in accordance with Section 6.4, any Batch in a Purchase Order that is cancelled under this Section 6.7 and for which the applicable Cancellation Fee has been paid by Customer will be considered a Batch "purchased" as of the Commencement Date in such cancelled Purchase Order.

6.8 Rescheduling. Lonza shall have the right to reschedule a Commencement Date of any Batch or Campaign once upon [***] prior written notice to Customer, provided that the resulting rescheduled Delivery Date is targeted not to exceed [***] later than the confirmed Delivery Date and for the purpose of calculating whether Customer has purchased the Minimum Quantity in accordance with Section 6.4, such rescheduled Batch will be considered "purchased" as of the original Commencement Date in the confirmed Purchase Order. If the Customer requests to change the Commencement Date, Lonza will make all reasonable attempts to accommodate the request; provided, however, in the event that this change would impact other projects scheduled for occupancy in the designated suite or suites, manufacture of the Customer's Batch or Campaign may be delayed until an adequate time period is available in the Facility schedule. Parties shall discuss in good faith the impact such rescheduling request has. Any delay requested by Customer of more than [***] shall be considered a cancellation of the Purchase Order and shall be subject to the Cancellation Fee set forth in Section 6.7.

6.9 Product Quantities. A Batch of [***] of Product (the "Target Quantity"), up to a maximum of [***] above or below, will be invoiced according to the Batch Price as set forth in Appendix A.

In case of quantities below [***] of the Target Quantity), Lonza shall invoice and Customer shall pay (i) the Batch Price minus (ii) the Batch Price multiplied by the number of kilograms produced less than [***] divided by the Target Quantity. For example: In case the quantity is [***])))).

In case of quantities above [***] of the Target Quantity) Lonza shall invoice and Customer shall pay (i) the Batch Price plus (ii) the Batch Price multiplied by the number of kilograms produced in excess of [***] divided by the Target Quantity. For example: In case the quantity is [***])))).

The Purchase Order shall be fulfilled if at least [***] of the Target Quantity is delivered. In the event that [***] or less of the Target Quantity for any Batch is delivered, (a) the Parties will negotiate in good faith the scheduling of the manufacture of a subsequent Batch, and Lonza will use its best efforts to prioritize the scheduling of such subsequent Batch so as to minimize disruption of Customer's supply of Product, and (b) at Customer's discretion, such subsequent Batch shall be considered a Batch "purchased" in the next calendar year for purposes of calculating whether Company has purchased the Minimum Quantity in accordance with Section 6.4.

7 Delivery and Acceptance

7.1 Delivery. Lonza shall deliver to Customer all documentation as set forth in the Quality Agreement and as is reasonably required to meet all applicable regulatory requirements of the Governmental Authorities, including without limitation Master Batch Records, Certificates of Analysis, deviations, and Batch records in accordance with the Quality Agreement (the "**Lonza Release**"). After the Lonza Release, [***] in accordance with **Appendix A** and Section 8. Customer shall be responsible for reviewing such documentation and for final release for delivery of the Product to Customer within [***] after Lonza Release in accordance with the Quality Agreement, and upon approval of such documentation by Customer, Lonza shall deliver the Product [***] on a date mutually agreed to by the Parties in accordance with Section 7.2 (the "**Release for Delivery**") and title and risk of loss shall transfer to Customer [***].

7.2 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at [***] expense, within [***] after Lonza Release or [***]. Lonza shall provide storage in accordance with the requirements set forth in the Quality Agreement on a bill and hold basis for such Batch(es) at [***] for up to [***]; provided that any additional storage beyond [***]. In addition to Section 8.2, below, [***] shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Batch for more than [***] after Release for Delivery. Within [***] following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

7.3 Acceptance/Rejection of Product.

7.3.1 Promptly following Lonza Release of a Batch, Customer shall inspect such Batch and shall have the right to test such Batch to determine compliance with the

Product Specifications. Customer shall notify Lonza in writing of any rejection of a Batch based on any claim that it fails to meet Specifications within [***] of Release for Delivery, after which time all unrejected Batches shall be deemed accepted. Customer shall inform Lonza in writing in case of concealed or latent defects (i.e. not discovered by routine quality control means), promptly upon discovery of such defects but no later than [***] after delivery of the Product.

7.3.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to it Batch samples for testing. Lonza may retain and test the samples of such Batch. In the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.3.3 Lonza shall Reprocess or Rework any Batch, as defined in the Quality Agreement, or, if Reprocessing or Reworking is not possible, replace any Batch that fails to conform with the Specifications (a "**Failed Batch**"). In the event that such failure of the Failed Batch is determined by the Parties or the independent laboratory in accordance with Section 7.3.2 to be attributable to the Manufacturing Process supplied to Lonza by Customer ("**AMAG Failed Batch**"), then such Reprocessing, Reworking or replacement will be at [***] cost, including the cost of Raw Materials and Necessary Consumables, according to a schedule mutually agreed to by the Parties, which shall in any event be as promptly as practicable.

In the event that it is determined by the Parties or the independent laboratory in accordance with Section 7.3.2 that such failure of the Failed Batch is not attributable to the Manufacturing Process supplied to Lonza by Customer ("**Lonza Failed Batch**"), then such Reprocessing, Reworking or replacement will be at [***] cost, including the cost of Raw Materials and Necessary Consumables, and according to a schedule mutually agreed to by the Parties, which shall in any event be as promptly as practicable. If Lonza is or will be unable to (i) Reprocess or Rework such Lonza Failed Batch and deliver the resulting Product within [***] of the Delivery Date, or (ii) replace such Lonza Failed Batch and deliver the resulting Product within [***] of the Delivery Date, then in either case Lonza shall instead, at Customer's discretion, refund the Batch Price of the Lonza Failed Batch to Customer. In the event that [***] or more consecutive Lonza Failed Batches occur during the Term, Customer may, at its discretion, terminate this Agreement.

Regardless of the remedy elected by Customer under this Section 7.3.3, for the purpose of calculating whether Customer has purchased the Minimum Quantity in accordance with Section 6.4, a Failed Batch shall be considered a Batch "purchased" on the Commencement Date of such Batch as specified in the Purchase Order.

Except for Lonza's indemnification obligations set forth in Section 11.1, Customer acknowledges and agrees that its sole remedy with respect to a Lonza Failed Batch is as set forth in this Section, and in furtherance thereof, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims.

7.4 **Failure to Supply**

7.4.1 If Lonza is or will be unable, for any reason (not including an event of Force Majeure under Section 14 hereof) to supply a Batch in accordance with the quantity and/or on the Delivery Date specified in a Purchase Order confirmed by Lonza in accordance with Section 6.3 or as rescheduled in accordance with Section 6.8 ("**Failure to Supply**"), Lonza shall immediately upon discovery notify Customer in writing of such circumstance. Within [***] of discovery of such Failure to Supply, Lonza shall notify Customer of the cause of such failure and shall propose a plan of remediation.

7.4.2 If Lonza is unable to remedy the Failure to Supply within [***] after the Delivery Date specified in the Purchase Order confirmed by Lonza in accordance with Section 6.3, then Customer may, at its discretion, cancel such Purchase Order, provided that in the event of such a cancellation, (i) the Cancellation Fee set forth in Section 6.7 shall not apply to such canceled Purchase Order, (ii) the Batch set forth in such canceled Purchase Order shall be considered a Batch "purchased" on the Commencement Date of such Batch as specified in the Purchase Order for purposes of calculating whether Company has purchased the Minimum Quantity in accordance with Section 6.4, and (iii) any Up-Front Payment paid by Customer to Lonza according to **Appendix A** shall be, at Customer's discretion, fully refunded to Customer or applied to the Batch Price for a subsequent Batch.

7.4.3 Lonza shall promptly notify Customer when Lonza can resume supply of Product in accordance with this Agreement and provide Customer with a date for Delivery of the Product in accordance with Customer's needs.

7.4.4 In the event that [***] or more consecutive Supply Failures occur during the Term, Customer may, at its discretion, terminate this Agreement.

8 Price and Payment

8.1 Pricing for the Services provided by Lonza are set out in, and based on the assumptions and information set out in **Appendix A**.

8.2 Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import, duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer.

8.3 All invoices are strictly net of any deduction and payment must be made within [***] of date of receipt of invoice. Customer will inform Lonza in writing if it disputes any invoice or amounts specified therein within [***] of its receipt thereof.

8.4 Any payments due hereunder which are not made within [***] after the due date of such payments shall be subject to default interest at the lesser of (i) rate of [***] per month or (ii) the [***], such interest to accrue on a day to day basis until full payment, provided that if any portion of an invoice is disputed by Customer on justified grounds,

Customer shall pay the undisputed amounts in accordance with the terms above, and the Parties shall use good faith efforts to resolve differences or discrepancies with regard to any disputed amount as soon as practicable.

8.5 Price adjustments. Not more than once per calendar year, Lonza may adjust the Batch Price in accordance with [***] increase for the previous calendar year, such increase not to exceed [***] in any calendar year, provided that Lonza provides Customer with sufficient documentation to substantiate such proposed increase. The new Batch Price reflecting any such adjustment shall be effective for any Batch for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment. In the event of an adjustment to the Batch Price under this Section 8.5, Lonza will submit a Change Order to the pricing to substantiate the change at least [***] prior to the proposed change, to be signed by both Parties.

8.6 Capital Equipment. Any capital equipment required for the performance of the Services shall be acquired on terms to be agreed by the Parties prior to commencement of the relevant Services.

9 Intellectual Property

9.1 Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party, including any improvements made thereto during the Services under this Agreement.

9.2 Subject to Section 9.3, Customer shall own all right, title, and interest in and to [***] (collectively, the "**New Customer Intellectual Property**"). For avoidance of doubt, New Customer Intellectual Property shall include [***].

9.3 Subject to Section 9.2, and subject to the license granted in Section 9.5, Lonza shall own all right, title and interest in [***] ("**New General Application Intellectual Property**"). For avoidance of doubt, New General Application Intellectual Property shall include [***].

9.4 Lonza agrees to assign and hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property. Customer agrees to assign and hereby assigns to Lonza all of its right, title and interest in any New General Application Intellectual Property. Customer shall execute, and shall require its personnel as well as its Affiliates, or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Lonza's ownership of the New General Application Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New General Application Intellectual Property.

9.5 Subject to the terms and conditions set forth herein (including the payment of the Price as required above), Lonza hereby grants to Customer a non-exclusive, world-wide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under the Lonza Background Intellectual Property and the New General Application Intellectual

Property to use, offer for sale, sell, export and import the Product manufactured under this Agreement.

9.6 Subject to the terms and conditions set forth herein, Customer hereby grants Lonza the non-exclusive right to use the Customer Information, Customer Background Intellectual Property and New Customer Intellectual Property during the Term solely for the purpose of fulfilling its obligations under this Agreement.

9.7 Customer has the right to transfer the Manufacturing Process to itself and any Third Party. Lonza shall provide reasonably necessary documents to complete such technology transfer and [***] (based on a full-time employee rate for such support) and expenses that are substantiated by sufficient documentation. If any Lonza Confidential Information, Lonza Background Intellectual Property, or New General Application Intellectual Property is useful in manufacturing the Product ("**Lonza Manufacturing-related IP**"), the Parties shall negotiate in good faith the terms and conditions of a [***] license under such Lonza Manufacturing-related IP for the manufacture of the Product, provided, additionally, that any such license shall be [***].

10 Representations and Warranties

10.1 Lonza represents and warrants that:

10.1.1 the Services shall be performed in accordance with all Applicable Laws;

10.1.2 except with respect to any development services and preparation batches as needed, the manufacture of Product shall be performed in accordance with cGMP and the Quality Agreement and will, at the date of delivery, meet the Specifications at the date of delivery and not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act, or any similar Applicable Laws;

10.1.3 it or its Affiliate holds, and shall maintain during the Term, all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility in accordance with Applicable Laws, the Quality Agreement and this Agreement;

10.1.4 it is under no contractual or other obligation or restriction that is inconsistent with its execution or performance of this Agreement, and it will not enter into any agreement, either written or oral, that would conflict with its responsibilities under this Agreement;

10.1.5 at the Effective Date of this Agreement and to the best of its knowledge, the performance and provision of Services will not infringe or misappropriate any patent, trade secret or other proprietary or Intellectual Property rights of any Third Party;

10.1.6 it will promptly notify Customer in writing if it becomes aware of a claim from a Third Party that its performance of the Services or the use, offer for sale, sale, import or export by the Customer of the Product manufactured under this Agreement infringes any Intellectual Property or other rights of any Third Party;

10.1.7 as of the Effective Date of this Agreement and to the best of its knowledge, any Third Party property that is either (i) used in Lonza's performance of the Services or (ii) incorporated into the Services or the Product manufactured under this

Agreement or (iii) subject to a sub-license from Lonza to Customer under the terms of this Agreement is under a valid license, with the right to sublicense, from the Third Party;

10.1.8 Lonza, its employees, affiliates, contractors, and agents used to perform Services under this Agreement, and any of their respective officers or directors, as applicable: (i) have not been debarred and are not subject to a pending debarment, (ii) are not disqualified and are not subject to a pending disqualification proceeding by any government or regulatory agency from performing the Services, and (iii) have not been convicted of a crime for which a person can be debarred under Section 335(a) or 335(b) of the Federal Food, Drug, and Cosmetic Act or under any analogous law or regulation under Applicable Laws, and are not subject to any such pending action upon execution of this Agreement; and Lonza will notify Customer immediately if Lonza, its employees, affiliates, contractors, and agents, or any person used to perform Services under this Agreement, or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Lonza's knowledge, is threatened; and

10.1.9 it has the necessary corporate authorizations to enter into and perform this Agreement.

10.2 Customer warrants that:

10.2.1 at the Effective Date of this Agreement and to the best of its knowledge, Lonza's use of the Customer Information and Customer Intellectual Property in connection with the performance of the Services shall not infringe any Third Party Intellectual Property rights;

10.2.2 Customer will promptly notify Lonza in writing if it becomes aware of a claim from a Third Party that Customer Information and Customer Intellectual Property or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property or other rights of any Third Party;

10.2.3 Customer has the necessary corporate authorizations to enter into this Agreement;

10.2.4 Customer, its employees, affiliates, contractors, and agents used to perform Services under this Agreement, and any of their respective officers or directors, as applicable: (i) have not been debarred and are not subject to a pending debarment, (ii) are not disqualified and are not subject to a pending disqualification proceeding by any government or regulatory agency from performing the Services, and (iii) have not been convicted of a crime for which a person can be debarred under Section 335(a) or 335(b) of the Federal Food, Drug, and Cosmetic Act or under any analogous law or regulation under Applicable Laws, and are not subject to any such pending action upon execution of this Agreement upon execution of this Agreement; and Customer will notify Lonza immediately if Lonza, its employees, affiliates, contractors, and agents, or any person used to perform Services under this Agreement, or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Customer's knowledge, is threatened.

10.3 The Parties hereby acknowledge that Customer is publicly traded on the NASDAQ National Market System under the symbol "AMAG". Further, each party is aware and will advise its employees, consultants and representatives who are informed of matters that are the subject of this Agreement, of the restrictions imposed by certain federal and state securities laws on the purchase or sale of securities by any person who has received or had access to material, nonpublic information concerning a company and on the communication of such information to any other person when it is reasonably foreseeable that such person is likely to purchase or sell such securities in reliance on such information.

10.4 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

11 Indemnification and Liability

11.1 Indemnification by Lonza. Lonza shall indemnify the Customer, its Affiliates, and their respective officers, employees and agents (" **Customer Indemnitees**") for any loss, damage, costs and expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the warranties given by Lonza in this Agreement, or (ii) Lonza's or Lonza's Indemnitees' negligence or intentional misconduct in performing any obligations under this Agreement, or (iii) any claims alleging that the Services (excluding use by Lonza of Customer Information and Customer Background Intellectual Property) infringe any Intellectual Property rights of a Third Party except, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by any Customer Indemnitees.

11.2 Indemnification by Customer. Customer shall indemnify Lonza, its Affiliates, and their respective officers, employees and agents (" **Lonza Indemnitees**") from and against any loss, damage, costs and expenses (including reasonable attorney fees) that Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the warranties given by Customer in this Agreement, or (ii) any claims alleging that Lonza's use of the Customer Intellectual Property or Customer Information in the performance of Services infringes any Intellectual Property rights of Third Parties, or (iii) Customer's or Customer's Indemnitees' negligence or intentional misconduct in performing any obligations under this Agreement, or (iv) the manufacture (except pursuant to this Agreement), use, sale, or distribution of any Product, including any claims of product liability; except, in each case, to the extent that such claims (A) resulted from the negligence, intentional misconduct or breach of this Agreement by any Lonza Indemnitees, or (B) resulted in any loss, damage, costs and expenses (including reasonable attorney fees) for which Lonza is liable pursuant to Clause 11.1 above.

11.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 11, it shall promptly notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents, shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 11. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of its obligation

to the indemnitee under this Clause 11 to the extent so prejudiced. The indemnitor shall not settle or compromise any claim in any manner that could have an adverse effect upon any indemnitee without such indemnitee's consent, which shall not be unreasonably withheld or delayed. The indemnitor shall not make any admission of liability in respect of any claim without the prior written consent of the indemnitee(s).

11.4 DISCLAIMER OF CONSEQUENTIAL DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR [***] ARISING FROM OR RELATED TO THIS AGREEMENT, EXCEPT TO THE EXTENT RESULTING FROM FRAUD, NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR A BREACH OF SECTION 12.

11.5 LIMITATION OF LIABILITY. LONZA'S LIABILITY FOR DAMAGES UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED, [***] UNDER THIS AGREEMENT IN THE [***] (OR IN THE CASE OF RELATED CAUSES OF ACTION, [***]), EXCEPT TO THE EXTENT RESULTING FROM INDEMNIFIABLE THIRD PARTY CLAIM UNDER CLAUSE 11.1 (i) OR (ii) ABOVE, LONZA'S FRAUD, NEGLIGENCE OR INTENTIONAL MISCONDUCT, OR A BREACH OF SECTION 12.

12 Confidentiality

12.1 Except as expressly permitted otherwise herein, the Party receiving Confidential Information (the " **Receiving Party**") agrees to strictly keep secret any and all Confidential Information received during the Term from or on behalf of the other Party (the "**Disclosing Party**") using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party, observed by the Receiving Party or its employees, agents, consultants, or representatives, or otherwise learned by the Receiving Party under this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary.

12.2 Notwithstanding the foregoing, Receiving Party may disclose to any courts and/or other authorities Confidential Information which is required to be disclosed pursuant to applicable governmental or administrative or public law, rule, regulation or order. In such case the Receiving Party will, to the extent legally permitted, (i) inform the other Party promptly in writing, (ii) cooperate with the Disclosing Party to secure confidential treatment for such Confidential Information, and (iii) seek to minimize the extent of Confidential Information which is required to be disclosed to the courts and/or authorities.

12.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which:

12.3.1 at the time of disclosure was publicly available; or

12.3.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party; or

12.3.3 as the Receiving Party can establish by contemporaneous written records, was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party; or

12.3.4 is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party, as evidenced by contemporaneous written records; or

12.3.5 is developed by the Receiving Party independently from and without use of the Confidential Information, as evidenced by contemporaneous written records.

12.4 The Receiving Party will use Confidential Information only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including, without limitation, with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party's request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

12.5 Each Party will restrict the disclosure of Confidential Information to such officers, employees, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement. Prior to disclosure to such persons, the Receiving Party shall bind its and its Affiliates' officers, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information.

12.6 The Receiving Party shall be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the officers, employees, consultants and representatives of itself or its Affiliates.

12.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 12 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief.

12.8 The confidentiality and non-use obligations imposed by this Agreement shall expire with respect to any particular item of a Disclosing Party's Confidential Information on the [***] anniversary of the date of disclosure of such Confidential Information (and in the case of trade secrets, until such time as such trade secrets are no longer accorded trade secret status under [***] law).

13 Term and Termination

13.1 Term. This Agreement shall commence on the Effective Date and shall be in effect until [***] (the "**Term**"). In order to avoid interruptions in the supply of Product to Customer, at least [***] prior to the expiration of the Term, the Parties shall meet (in person or telephonically) to discuss whether or not to extend the Term of this Agreement or to agree in good faith on a new agreement, which may include revisions to the following terms:

13.1.1 an annual minimum supply quantity (kilograms or Batches) Customer undertakes to purchase from Lonza;

13.1.2 a minimum % of Customer's annual demand that Customer undertakes to purchase from Lonza; and

13.1.3 the option for Lonza to produce the Product in a dedicated manufacturing asset.

13.2 Termination. This Agreement may be terminated as follows:

13.2.1 by either Party if the other Party breaches a material provision of this Agreement and fails to cure such breach within [***] for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such [***] (or [***] for non-payment) period may be extended only if mutually agreed to by the Parties if the identified breach is incapable of cure within [***] (or [***] for non-payment) and if the breaching Party promptly provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure;

13.2.2 by Customer, if the Product does not receive FDA approval and if Customer notifies Lonza in writing, within [***] that it wishes to terminate the Agreement for that reason;

13.2.3 by Customer, if Customer is required to withdraw the Product from the market for regulatory or health and safety reasons, on [***] prior written notice to Lonza;

13.2.4 by either Party, immediately, if the other Party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has a receiver appointed for a substantial part of its assets, provided that, in the case of an involuntary proceeding, such other Party may not terminate this Agreement if the petition is dismissed within [***] of filing; or

13.2.5 by Customer pursuant to Section 7.3.3, 7.4.4 or 14.

13.3 Consequences of Termination.

13.3.1 In the event of termination hereunder by Lonza under Section 13.2.1, or 13.2.4 Lonza shall submit to Customer an invoice, together with sufficient substantiating documentation, for (i) any applicable [***] and (ii) any applicable [***]. Customer shall pay such invoice in accordance with Section 8. At Customer's direction, with regard to any [***].

13.3.2 In the event of termination hereunder by Customer under Clause 13.2.2, or 13.2.3, (i) any Purchase Order(s) issued prior to the termination date that have not been fulfilled will be cancelled and such cancelled Purchase Orders shall not be subject to the Cancellation Fee set forth in Section 6.7, and (ii) Lonza shall submit to Customer an invoice, together with sufficient substantiating documentation, for (a) the [***], and (b) [***] as set forth in Section 6.4, if applicable. Customer shall pay such invoice in accordance with Section 8. At Customer's direction, with regard to any [***].

13.3.3 In the event of termination hereunder by Customer under Clause 13.2.1, 13.2.4 or 13.2.5, (i) any Purchase Order(s) issued prior to the termination date that have not been fulfilled will be cancelled and such cancelled Purchase Orders shall not be subject to the Cancellation Fee set forth in Section 6.8, (ii) any [***], and (iii) [***]. In such event, Customer shall compensate Lonza only for [***].

13.3.4 In the event of termination by either Party, each Party agrees to return or destroy the other Party's Confidential Information in accordance with Clause 12.4.

13.4 Survival. Sections 2.5, 4, 5, 8, 9, 10, 11, 12, 13.3, 13.4, 15.1, 15.3, 15.4, 15.5 and 15.6 shall survive the termination or expiration of this Agreement.

14 Force Majeure

14.1 If either Party is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to the other Party specifying the matters constituting Force Majeure together with such evidence as the affected Party reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, the affected Party shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue, provided that such Party is obligated to mitigate damages and to use best efforts to resume the fulfilment of its contractual obligations as soon as reasonably possible. Provided that, if such Force Majeure persists for a period of [***] or more, the Party not affected by such force majeure may terminate this Agreement by delivering written notice to the affected Party, with immediate effect.

14.2 "Force Majeure" shall be deemed to include any reason or cause beyond a Party's reasonable control affecting the performance by the Party of its obligations under the Agreement, including, but not limited to, acts of God, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, or terrorists acts.

14.3 Force Majeure affecting services or production at Lonza's Affiliates shall be regarded as an event of Force Majeure.

15 Miscellaneous

15.1 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the Purpose. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

15.2 Amendments/Assignment. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. Lonza may instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement only with prior written consent from Customer, but Lonza shall remain fully responsible in respect of those obligations. Subject thereto, neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) either Party may assign

this Agreement to (i) any Affiliate of such Party or (ii) any third party in connection with the sale or transfer (by whatever method, including merger, consolidation, acquisition or other form of business combination) of all or substantially all of the assets of the business related to the Facility or providing the Services in the case of Lonza, or all or substantially all of the assets related to the Product in the case of Customer, and (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer. For purposes of this Clause 15.2, the terms "assign" and "assignment" shall include, without limitation (i) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (ii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

15.3 Notice. All notices must be written and sent to the address of the Party first set forth above. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile or electronic mail, (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

15.4 Public Disclosures. It is understood that each Party may desire or be required to issue press releases or disclosures to the SEC or other applicable agency relating to this Agreement or activities hereunder. The Parties shall consult with each other reasonably and in good faith with respect to text and timing of such press releases and disclosures prior to the issuance thereof, provided that (i) neither Party may unreasonably withhold, condition or delay consent to such press releases or such disclosures to the SEC or other applicable agency, and (ii) either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by applicable laws or regulations, provided that each Party may make any such filing it reasonably determines necessary under such applicable laws and regulations. After any initial press releases related to this Agreement, either Party may disclose, without the other Party's consent, the existence of this Agreement, the identity of the other Party, and the terms of the Agreement which have already been publicly disclosed in accordance herewith. Notwithstanding the foregoing, Lonza shall not use the name of Customer, its Affiliates, or the names of their employees or representatives in any advertising materials without prior written consent of Customer, and Customer shall not use the name of Lonza, its Affiliates, or the names of their employees or representatives in any advertising materials without prior written consent of Lonza.

15.5 Authorized Disclosures. Customer may disclose the terms of this Agreement to any actual or potential acquiror or licensee to the Product, provided that: (i) such disclosure is solely for the purpose of such Third Party evaluating such acquisition or license opportunity with Customer; (ii) Customer redacts the financial terms of this Agreement (but Customer shall have the right to disclose the Batch Prices to any bona fide potential or actual acquirer or licensee who would bear and/or share the Batch Prices for the Product). Any party to whom such disclosure is made shall be under written obligations of confidentiality and non-use at least as stringent as those herein.

15.6 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of [***]. The Parties agree to submit to the jurisdiction of the courts of [***].

15.7 Entire Agreement. This Agreement and its Appendices contain the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for purposes of this Agreement.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Manufacturing Services Agreement to be executed by its duly authorized representative effective as of the date written above.

LONZA LTD

By: /s/ Bart A. M. Van Aarnhem
Name Bart A. M. Van Aarnhem
Title Senior Legal Counsel

By: /s/ Cordula Altekruger
Name Cordula Altekruger
Title Senior Legal Counsel

AMAG PHARMACEUTICALS, INC
By: /s/ William K. Heiden
Name William K. Heiden
Title CEO

Product Pricing

Parties agree that the Batch Price shall be:

Product Volume	Price per Batch ([***])
[***] Batches per Campaign	[***] per Batch
Additional Batches: [***] (or more) per Campaign	[***] per Batch

Payment terms:

- Lonza shall invoice and Customer shall pay [***] of the Batch Price upon confirmation of the binding Purchase Order in accordance with Section 6.3, for facility reservation, Raw Materials procurement, manufacturing and preparation (the "**Up-Front Payment**").
- Lonza shall invoice and Customer shall pay [***] of the Batch Price upon delivery of the Batch.
- Invoicing and payment shall be in accordance with Section 8.

[***], as defined in this Agreement.

[***] as defined in Section 1. Lonza will submit an invoice to Customer for the Specialty Material and Specialty Material Fee in accordance with Section 2.9, and Customer will pay such invoice in accordance with Section 8.

Additional Work Scope:
Any additional project needs that are not specifically called out within this Agreement or the Quality Agreement shall be invoiced and billed under a separate work order.

APPENDIX B

Project Plan

APPENDIX C

Quality Agreement

[Attached]

APPENDIX D

Specifications

[Attached]

APPENDIX E
Change Order

Change Order – [*insert number*]

Dated: [***insert date****]*

This is a Change Order of the purposes of Manufacturing Services Agreement between **Lonza Ltd.** and **AMAG Pharmaceuticals, Inc.** dated _____[*insert date*] (the "**Agreement**").

Terms used but not defined in this Change Order shall have the meaning given to them in the Agreement.

Effective Date: Day, Month, Year
End Date: Day, Month, Year

Current Price: [***]

Revised Price: [***]

New Total Cost (if applicable): [***]

The following reasons have caused the Price to change (increase or decrease):

1.

EXECUTED as an **AGREEMENT**

Signed by **LONZA LTD.**	Signed for and on behalf of **AMAG PHARMACEUTICALS, INC.**
_____ Signature	_____ Signature
_____ Name	_____ Name
_____ Title	_____ Title
_____ Date	_____ Date

Exhibit 10.31

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

SUPPLY AGREEMENT

effective as of 20 December 2018 ("**Effective Date**")

between

AMAG Pharmaceuticals, Inc., 1100 Winter Street, Waltham, MA 02451, USA

- "**AMAG**" -

and

Ypsomed AG, Brunnmattstrasse 6, CH-3401 Burgdorf, Switzerland

- "**Ypsomed**" –

For Autoinjectors for the Administration of Bremelanotide

Preamble

a) Palatin Technologies, Inc., 4-B Cedar Brook Drive, Cranbury, New Jersey 08512, USA (" **Palatin**") developed a subcutaneous injection formulation of Bremelanotide (as defined below) for use in female sexual dysfunction;

b) Palatin licensed to AMAG the rights to develop and commercialize Bremelanotide in North America and to manufacture Bremelanotide worldwide;

c) AMAG, Palatin and Ypsomed have entered into a three way Confidentiality and Non-Use Agreement, effective as of 6 March 2017 (hereinafter "**Confidentiality Agreement**"), and, under such Confidentiality Agreement, have discussed the potential use of a customized version of the YpsoMate (as defined below) for the injection of Bremelanotide;

d) Palatin and Ypsomed entered into an agreement, dated as of 8 June 2012, with respect to the variant specific customization of the YpsoMate for the administration of pre-filled Bremelanotide syringes ("**Customization Proposal**");

e) Palatin and Ypsomed entered into an agreement, dated as of 30 January 2015, with respect to an industrialization project for the initializing of the commercial supply of the customized autoinjectors ("**Industrialization Proposal**");

f) AMAG and Ypsomed entered into Terms and Conditions dated 14 June 2017 governing the purchase of Component Sets (as defined therein) pursuant to AMAG purchase order numbers 71635 and 71636 (the "**Terms and Conditions**") and it is intended that the terms and conditions of this Agreement will govern the supply of such Component Sets to AMAG; and

g) AMAG and Ypsomed now wish to agree on the terms and conditions of the commercial supply of the Components (as defined hereunder) used to assemble the customized YpsoMate injection device.

Now, therefore, in consideration of the above, AMAG and Ypsomed agree as follows:

1. Definitions

"Affiliate"	shall mean any corporation or other entity that directly or indirectly controls, is controlled by, or is under common control with AMAG or Ypsomed, as applicable. For the purpose of this Agreement, "control" shall mean the direct or indirect ownership of fifty percent (50%) or more of the outstanding shares or other voting rights of the subject entity for the election of directors.
"Agreement"	shall mean this Supply Agreement, together with all Appendices, as amended or modified from time to time in accordance with the terms hereof.
"Annual Minimum Quantity"	shall have the meaning set forth in **Appendix 3**.
"Appendix", "Appendices"	shall mean the addenda, exhibits, schedules and/or supplements to this Agreement, as amended or modified from time to time in accordance with the terms hereof.
"Applicable Laws"	as of the Effective Date, Applicable Laws shall mean applicable statutes, laws and regulations of the United States, the European Union, Switzerland, Canada, Mexico, China, and South Korea relevant to the services under this Agreement and the manufacture of the Components in the Territory, and shall include, without limitation, cGMP; FDA 21 CFR Part 820; European Council Directive 93/42/EEC; ISO 13485:2003; ISO 14971:2007 and any additional, successor or replacement statutes, laws and regulations thereto, which come into effect during the Term of this Agreement. The statutes, laws and regulations of additional countries or jurisdictions in the Territory may be added to the Applicable Laws upon mutual agreement of the Parties in accordance with Section 4.9.
"Authority"	shall mean the Food and Drug Administration ("FDA") (or any successor agency thereto) in the United States, the European Medicines Agency EMA (or any successor agency thereto) in Europe, Health Canada in Canada, and/or the applicable equivalent regulatory agency or entity, governmental or non-governmental, having the responsibility, jurisdiction and authority for the grant of Authorizations in Mexico, China, South Korea, and any other country or jurisdiction in the Territory as mutually agreed to by the Parties in accordance with Section 4.9.
"Authorizations"	shall mean the authorizations for the manufacture, labeling, packaging, importation, promotion, marketing, offer to sell, sale, distribution and use of the Bremelanotide Devices in the Territory, and any amendments or modifications thereto.
"Binding Forecast"	shall have the meaning set forth in Section 7.2.
"Bremelanotide"	shall mean Palatin's injectable drug substance licensed to AMAG in which the active pharmaceutical ingredient is the peptide Ac-Nle-*cyclo*(-Asp-His-D-Phe-Arg-Trp-Lys)-OH.

"Bremelanotide Device"	shall mean the customized YpsoMate for the injection of Bremelanotide consisting of the Components, a syringe containing Bremelanotide and accessories, if any, as such Bremelanotide Device is further defined in the Specifications.
"Price Change Order"	shall mean a document in the format provided in **Appendix 5** provided by Ypsomed to AMAG outlining a proposed adjustment (increase or decrease) to the Purchase Price and the reasons for such adjustment, such document to be reviewed and signed by both parties to enable such adjustment to take effect.
"cGMP"	shall mean the current Good Manufacturing Practice requirements related to the methods used in, and the facilities and controls used for, developing, customizing, manufacturing, testing, processing, packaging, labeling, storing, installing, and servicing of the Components as specified in the Medical Device Directive 93/42/EEC and ISO 13485, as amended or modified from time to time.
"Components"	shall mean the individual parts and subassemblies of Ypsomed's customized YpsoMate, as they are described in the Specifications. For the avoidance of doubt, Components shall not include the syringe containing Bremelanotide.
"Component Set"	shall mean a complete set of all Components for use by AMAG or its designee to assemble of one Bremelanotide Device.
"Delivery"	shall have the meaning set forth in Section 8.1.
"Delivery Date"	shall have the meaning set forth in Section 7.4.
"Hidden Defect"	shall mean any Component's failure (i) to have been manufactured in accordance with this Agreement, including, without limitation, cGMP in effect at the time of manufacture, or (ii) to conform in all material respects to the Specifications in effect at the time of manufacture, to the exclusion of any failure which was or could have been identified through commercially reasonable and adequate inspection and testing based on mutually agreed inspection criteria as set out in the Specifications and according to Section 9.1.
"Initial Inspection"	shall have the meaning set forth in Section 9.1.
"Initial Term"	shall have the meaning set out in Section 21.1.
"Intellectual Property Rights"	shall mean any and all rights in or to inventions, discoveries, know-how, trade secrets, trade names, confidential information (including know-how), domain names, works of authorship reduced to a tangible medium of expression, including, without limitation, technical data and software, industrial and other design rights, patents, trademarks, copyrights, database rights, and any other intellectual property, in each case, whether registered or unregistered or patentable or not, including rights to applications or registrations for any of the foregoing.
"Party", "Parties"	shall mean AMAG and/or Ypsomed, as applicable.
"Pricing Tier"	shall have the meaning set forth in **Appendix 3**.
"Purchase Order"	shall have the meaning set forth in Section 7.3.
"Purchase Price"	shall mean the prices per Component Set according to the price list as set out in **Appendix 3**.
"Quality Agreement"	shall mean the quality agreement set out in **Appendix 2**, as amended or modified from time to time in accordance with the terms hereof.
"Rolling Forecast"	shall have the meaning set forth in Section 7.2.
"Subsequent Term"	shall have the meaning set out in Section 21.1.

"Specifications"	shall mean the specifications for the Components and Component Sets, as well as certain requirements regarding the assembly of the Bremelanotide Device, all as further described in **Appendix 1**, as amended from time to time in accordance with the terms hereof.
"Territory"	shall - for the purpose of this Agreement - include the countries enumerated in the definition of Applicable Laws and Authority hereinabove; provided however that Ypsomed acknowledges that AMAG has the right to use, register, and market the Bremelanotide Device worldwide. Accordingly, statutes, laws and regulations of additional countries or jurisdictions may be added to the Applicable Laws and the respective further countries will be included to the definition of Territory pursuant to Section 4.9.
" YpsoMate"	shall mean the technical platform of a two-step disposable autoinjector developed by Ypsomed for use with various drug substances contained in a syringe.

2. Appendices

2.1 The following Appendices are incorporated into this Agreement by this reference:

No.	**Appendix**	**Subject/Content (inter alia)**
1	Specifications	Specifications for Component and Component Sets
2	Quality Agreement	Quality Agreement for Component Sets: change control, complaint handling, audits, regulatory issues
3	Commercial Terms	Pre-commercial supply & capacity reservation, forecast and ordering procedure, Purchase Prices, minimum purchase quantities
4	Price Change Order	Form to be used in the event of a change to the Purchase Price based on the template format set out in Appendix 4.

2.2 **Order of Precedence.** The following interpretation rule shall apply: (a) any amendments or modifications to this Agreement or the Appendices shall prevail over this Agreement or the Appendices themselves, (b) this Agreement shall prevail over the Appendices, except with respect to matters relating to the quality of the Components, the Quality Agreement shall prevail over this Agreement, and (c) this Agreement shall prevail over the Terms and Conditions.

3. Amendments and/or Modifications

3.1 Either Party may at any time recommend an amendment and/or modification to this Agreement or the Appendices, including the Specifications. Amendments and/or modifications to this Agreement or the Appendices shall only be effective upon a signed written agreement between the Parties. The Appendices shall be subject to version control to document any changes made to them. Amendments and/or modifications to the Specifications shall be made in accordance with the change control provisions of the Quality Agreement.

3.2 Neither Party shall unreasonably withhold, condition or delay its consent to any amendments and/or modifications recommended in good faith by the other Party in relation to compliance with changes in Applicable Laws, including, without limitation, cGMP, or changes in the regulatory environment. In the event Ypsomed modifies the YpsoMate and determines in good faith that corresponding modifications to any Component is necessary or beneficial, then AMAG shall approve such modifications,

provided that such modifications are made in accordance with the change control provisions of the Quality Agreement. Notwithstanding the foregoing, with respect to each proposed amendment and/or modification to the Agreement or the Appendices, the Parties shall discuss in good faith the cost and time implications associated therewith. The requirements and the procedure for change control are set out in the Quality Agreement.

3.3 In the event that the Parties agree to change the Specifications in accordance with the change control provisions of the Quality Agreement, Ypsomed shall: (x) use commercially reasonable efforts to implement such change as soon as reasonably practicable; (y) be responsible for ensuring that all Components manufactured following such change meets the Specifications as amended; and (z) provide AMAG with all information and reasonable assistance with respect to the manufacture of the Components in connection with such change needed to amend any regulatory filings maintained with respect to the Bremelanotide Device. To the extent such change is a result of a change in Applicable Law or a discretionary change requested by [***], AMAG shall [***] of implementing the changes, otherwise, Ypsomed shall [***].

3.4 The Specifications are not physically attached to this Agreement, since they are kept in the Design History File (DHF) which is maintained at Ypsomed's premises. Ypsomed shall provide AMAG with a copy of the Specifications.

4. Commercial Supply

4.1 Ypsomed shall manufacture the Component Sets in accordance with the terms of this Agreement and the Specifications attached as **Appendix 1**.

4.2 Subject to the terms of this Agreement, AMAG shall purchase Component Sets from Ypsomed and Ypsomed shall supply AMAG with Component Sets.

4.3 In the event AMAG decides during the Term of this Agreement to develop (directly or indirectly) a new injection device for the administration of Bremelanotide, AMAG shall give Ypsomed notice thereof prior to issuing an invitation to tender or commencing negotiations with any third party in respect of developing such injection device. If, within [***] after AMAG gives such notice to Ypsomed, Ypsomed requests, in writing, an opportunity to submit a proposal with respect to the development, customization, manufacture and supply of such injection device, AMAG shall provide Ypsomed with the desired specifications on a confidential basis and negotiate in good faith with Ypsomed regarding any such proposal by Ypsomed. For the avoidance of doubt, AMAG shall be free to engage in parallel good faith negotiations, and to enter into a definitive agreement, with any third party with respect to the development, customization, manufacture and supply of the new injection device.

4.4 Ypsomed retains all rights to promotion, import, advertisement, distribution, offering for sale and sale in the Territory of the YpsoMate and/or customized variations thereof as well as other disposable injection systems, other than the Component Sets being supplied to AMAG pursuant to this agreement, to itself, its customers or distributors.

4.5 The commercial terms for the supply of Component Sets are set out in **Appendix 3**.

4.6 [***] at the Purchase Price set out in **Appendix 3**. The Purchase Price is firm until [***]. Thereafter, the Purchase Price is subject to adjustments, however no more than on [***] basis, to reflect increases or decreases in raw material prices and other related cost influencing factors that are not under Ypsomed’s control; provided, however, that notwithstanding the foregoing, the percentage increase or decrease in

the Purchase Price shall not exceed the lesser of (i) the percentage increase in the [***] since the then-current Purchase Price was established and (ii) [***]. In the event of a proposed adjustment to the Purchase Price under this Section 4.6, Ypsomed will in good faith submit a Price Change Order to AMAG to substantiate the adjustment, and such adjustment shall not take effect until the Price Change Order is signed by both Parties.

4.7 Throughout the Term, Ypsomed agrees to use its commercially reasonable efforts to identify and target all potential areas of cost improvement. [***]. In the event of a proposed adjustment to the Purchase Price under this Section 4.7, Ypsomed will in good faith submit a Price Change Order to AMAG to substantiate the adjustment, and such adjustment shall not take effect until the Price Change Order is signed by both Parties.

4.8 Beginning in [***], AMAG shall purchase at least the Minimum Annual Quantity of Component Sets in each remaining calendar year during the Initial Term as set out in **Appendix 3**. For the purpose of determining whether AMAG is in compliance with this Section 4.8, a Component Set is considered "purchased" as of the agreed Delivery Date in the respective Purchase Order, provided however that such ordered Component Sets will have been duly paid by AMAG (during such calendar year or, as applicable, at a later stage in accordance with the terms of this Agreement). If AMAG does not purchase the Annual Minimum Quantity in a calendar year in accordance with this Section 4.8, AMAG shall pay Ypsomed at the end of such calendar year, upon receipt of an invoice and reasonable supporting documentation in accordance with Section 6, an amount equal to (a) the difference between (i) the Annual Minimum Quantity for such calendar year and (ii) the aggregate number of Component Sets purchased by AMAG (or its Affiliates or licensees) during such calendar year (such amount, the "**Shortfall**"), *multiplied by* [***] of the Unit Price per Component Set as set forth in **Appendix 3** (the "**Shortfall Fee**"). In the event that AMAG disputes the amount of the Shortfall Fee due under this Section 4.8, AMAG shall provide Ypsomed with written notice of such dispute within [***] of receipt of such invoice. If no written notice is provided by AMAG within [***] of receipt of such invoice AMAG shall be deemed to have given its approval to the Shortfall Fee.

4.9 The Parties - each for its obligations under this Agreement - shall comply with all Applicable Laws. The Parties acknowledge that AMAG has the right to market, sell and distribute the Bremelanotide Device in further countries than those enumerated in the definition of Applicable Laws and Authority in Section 1 subject to and in accordance with the terms of this Agreement. Accordingly, AMAG has the right to reasonably request Ypsomed to comply with any applicable laws other than the Applicable Laws as such laws are identified and deviate from the Applicable Laws and their requirements communicated in writing by AMAG to Ypsomed and to adjust the term Territory under Section 1 accordingly. In the event of any additional, successor or replacement applicable laws affecting Ypsomed's performance under this Agreement (including, without limitation, in respect of costs, timelines, facilities, equipment, processes, materials or systems), Ypsomed shall have the right to request and the Parties shall negotiate in good faith an amendment and/or modification pursuant to Section 3. For clarity, in the event that any additional, successor or replacement applicable laws that AMAG wishes Ypsomed to comply with, does not affect Ypsomed's performance under this Agreement, such additional applicable laws shall become automatically part of the Applicable Laws without any need for an amendment and/or modification pursuant to Section 3.

4.10 The Parties agree that the terms and conditions of this Agreement will govern the manufacture and supply of Component Sets pursuant to AMAG purchase order numbers 71635 and 71636, and such Component Sets are deemed to be Component Sets manufactured by Ypsomed and supplied to AMAG under this Agreement. In the event of a conflict between this Agreement and the Terms and Conditions, this Agreement shall control.

5. Engagement of Subcontractors and Designees, Final Assembly & Packaging

5.1 Ypsomed shall be entitled to engage subcontractors in accordance with the Quality Agreement, including (i) such subcontractors involved in the development and manufacture of the YpsoMate platform ("**YpsoMate Subcontractor**"), and (ii) such other subcontractors which are solely and specifically involved in the manufacture of Component Sets under this Agreement, not being YpsoMate Subcontractors ("**Specific Subcontractor**"). The engagement of a Specific Subcontractor by Ypsomed requires AMAG's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed. Ypsomed shall not be relieved from its obligations hereunder and assumes full liability for the performance and all acts and/or omissions of its subcontractors as if they were its own performance and acts and/or omissions. Ypsomed shall ensure that each subcontractor is aware of and bound by the applicable provisions of this Agreement.

5.2 Ypsomed shall deliver the Component Sets in bulk packaging as set out in the Specifications (**Appendix 1**). AMAG shall be responsible for the final assembly and packaging of the Bremelanotide Device. AMAG shall be entitled to engage designees for final assembly and/or packaging of the Bremelanotide Device, provided that AMAG shall not be relieved from its obligations hereunder and that it assumes full liability for the performance and all acts and/or omissions of its designees as if they were its own performance and acts and/or omissions.

5.3 The Parties agree that Ypsomed and its subcontractors, and AMAG and its designees, as applicable, may need to discuss aspects of this Agreement with each other, (e.g., in respect of AMAG's designee's final assembly of the Component Set into the Bremelanotide Device). For such purpose, Ypsomed and its subcontractors, as applicable, on the one hand, and AMAG and its designees, as applicable, on the other hand, may directly disclose to, and receive from, each other confidential information of the other Party. Each Party shall ensure that its designees or its subcontractors, as applicable, are bound by appropriate confidentiality obligations no less stringent than the confidentiality obligations set out in this Agreement.

6. Payment

6.1 All costs and prices invoiced under this Agreement are specified in [***]. All payments due to Ypsomed by AMAG under this Agreement are expressed as net amounts and AMAG shall be liable to pay any applicable sales taxes, value added taxes and duties.

6.2 With respect to each undisputed invoice under this Agreement, AMAG shall make payments to Ypsomed under this Agreement in immediately available funds to the bank account designated by Ypsomed from time to time, within [***] after the date of the invoice.

6.3 Any payments due hereunder which are not made within [***] after the due date of such payments shall be subject to default interest of [***] per [***] period on the unpaid amount until paid in full. Notwithstanding any right to terminate this Agreement

for AMAG's material breach as set out in Section 21.2, if any payment due hereunder is not made within [***] after the date on which such payment is due, Ypsomed shall provide written notice to AMAG, and AMAG shall use commercially reasonable efforts to remedy such failure. If any portion of an invoice is disputed by AMAG on justified grounds, AMAG shall pay the undisputed amounts in accordance with the terms above, and the Parties shall use good faith efforts to resolve differences or discrepancies with regard to any disputed amount as soon as practicable.

7. Forecasts and Purchase Orders

7.1 On the Effective Date and before January 1 of each year thereafter, AMAG shall provide Ypsomed with a written forecast for [***] of AMAG's estimated requirements for Component Sets (the "**Long Range Forecast**"). Such Long Range Forecasts shall only be used for capacity planning and determination purposes as set out herein.

7.2 On the Effective Date and on or before of each January 1, April 1, July 1 and October 1 during the Term, AMAG shall provide Ypsomed with a written [***] rolling forecast of AMAG's estimated requirements for Component Sets (the "**Rolling Forecast**"). Such Rolling Forecasts shall include binding and non-binding periods, [***] (the "**Binding Forecast**"). The non-binding portion of each Rolling Forecast shall only be used for capacity planning and determination purposes as set out herein. In its Rolling Forecast, AMAG shall, to the extent practicable, level out potential variations in the forecasted amounts for consecutive quarters (in any case for at least the first [***] covered by the Rolling Forecast) to enable continuous manufacture and resource planning at Ypsomed.

7.3 On or before each January 1, April 1, July 1 and October 1 during the Term, AMAG shall submit to Ypsomed a purchase order specifying the number of Component Sets and the requested delivery date(s) for the second quarter thereafter in accordance with the Binding Forecast ("**Purchase Order**"), and in each case no later than [***] prior to the requested delivery date(s) specified in the Purchase Order.

7.3 In the event of any conflict between a Purchase Order submitted by AMAG and this Agreement, this Agreement shall prevail, unless Ypsomed expressly approves such conflict or accepts such Purchase Order in writing.

7.4 Ypsomed shall acknowledge and confirm each Purchase Order in writing within [***] of receipt, provided that AMAG has submitted the Purchase Order in accordance with the terms of this Agreement. However, (a) in no event shall Ypsomed be required to supply quantities of Component Sets in excess of the Applicable Capacity unless otherwise agreed by the Parties, and (b) if the quantity of ordered Component Sets in a Purchase Order exceeds the quantity set out in the Rolling Forecast by more than [***] for the respective quarter, the Parties will agree on the delivery date for such excess quantities on a case-by-case basis. If Ypsomed is unable to deliver all of the Component Sets by the requested date of Delivery in the Purchase Order, Ypsomed shall so notify AMAG within [***] of receipt of the Purchase Order, and the Parties shall negotiate in good faith an alternate date of Delivery as close to the requested date of Delivery as is commercially reasonable, provided that in no event shall such alternate date be more than [***] after the requested date of Delivery in the Purchase Order. Upon confirmation by Ypsomed, each Purchase Order will be regarded by the Parties as a binding commitment by Ypsomed to manufacture and Deliver to AMAG the relevant number of Component Sets on the delivery date (such agreed upon delivery date being the "**Delivery Date**").

8. Delivery

8.1 Ypsomed shall deliver the number of Component Sets set out in the relevant Purchase Order by the Delivery Date (" **Delivery**"), provided that over-delivery or under-delivery of up to [***] of the ordered amount shall be allowed. Component Sets shall be delivered to AMAG FCA Ypsomed's manufacturing facility indicated in the Quality Agreement (Incoterms 2010) and title shall pass upon Delivery at such facility.

8.2 Ypsomed shall notify AMAG of any expected delay in Delivery and will make commercially reasonable efforts to effect Delivery as quickly as possible. The Parties shall, if requested by AMAG, renegotiate the date(s) of Delivery of all placed Purchase Orders following a delayed Delivery. Ypsomed may, upon AMAG's prior written consent, make partial deliveries to maintain continuous supply. In case Ypsomed anticipates that it may not be able or is unable to Deliver all Components Sets by more than [***] after the Delivery Date set forth in a Purchase Order, Ypsomed shall notify AMAG in writing immediately and provide an explanation thereof. Ypsomed shall discuss with AMAG potential remedies and propose as soon as reasonably possible a mitigation plan to AMAG's reasonable satisfaction, which will include concrete measures in line with Ypsomed's business continuity plan, such as the introduction or increase of shift work, an internal second source option, or safety stock provisions; as well as any other measures in order to provide a fast and secure recovery of the supply of Component Sets. Notwithstanding the foregoing, if Ypsomed is or will be unable for any reason to deliver all Component Sets within [***] of the Delivery Date in the respective Purchase Order, then AMAG may, at its sole discretion, (i) cancel such Purchase Order without penalty to AMAG and the number of Component Sets in such cancelled Purchase Order shall be counted toward the Annual Minimum Quantity for the calendar year in which the cancelled Purchase Order was submitted, or (ii) accept Delivery of the Component Sets on a delivery date mutually agreed to by the Parties.

8.3 Ypsomed will convey good title to the Component Sets to AMAG on the date of Delivery, free and clear of any lien or encumbrance.

9. Inspection, Notification of Defects

9.1 Upon receipt of a lot of Component Sets and all release documentation at AMAG or its designee's premises, AMAG or its designee acting on behalf of AMAG shall carry out commercially reasonable and adequate inspection and testing of the lot of Component Sets based on mutually agreed inspection criteria as set out in the Specifications (the "**Initial Inspection**"). If any Component Sets fail Initial Inspection, then AMAG shall notify Ypsomed within [***] after the arrival of such Component Sets at AMAG's or its designee's premises (such notice, a "**Failure Notice**"). If AMAG does not so notify Ypsomed, then such Component Sets shall be deemed accepted by AMAG. In the event AMAG rejects any Component Sets under this Section 9.1, AMAG shall identify such Component Sets and their date of Delivery and provide Ypsomed with a report (including photos if applicable) on the nature of the alleged defect. AMAG shall hold any such Component Sets for inspection by Ypsomed or, upon Ypsomed's written request and at [***] sole cost, shall return such Component Sets to Ypsomed, whereas [***] shall reimburse the cost of returning such Component Sets to Ypsomed in the event the respective Component Sets are determined not to have failed Initial Inspection.

9.2 If at any time within a period of [***] after Delivery of a Component Set to AMAG or its designee AMAG discovers an alleged Hidden Defect, AMAG shall notify Ypsomed within [***] after the discovery of such Hidden Defect. AMAG shall identify the relevant Component Sets and their date of Delivery and provide Ypsomed with a report (including photos if applicable) describing the nature of the alleged Hidden Defect. AMAG shall hold any such Component Set for inspection by Ypsomed or, upon Ypsomed's written request and at [***] sole cost, shall return such Component Sets to Ypsomed, whereas [***] shall reimburse the cost of returning such Component Sets to Ypsomed in the event the respective Component Sets are determined to comply with the product warranty set out in Section 11.1. Except to the extent AMAG provides the notice of an alleged Hidden Defect to Ypsomed in accordance with this Section 9.2, the Delivered Component Sets shall be deemed to be accepted by AMAG.

10. Remedy and Liability for Defects

10.1 In the event one or more Component Sets fails Initial Inspection under Section 9.1, has a Hidden Defect under Section 9.2, or is determined not to comply with the product warranty set out in Section 11.1, provided that AMAG provided proper notice to Ypsomed within the agreed time period under Section 9.1 or Section 9.2, as applicable, and subject to Section 11.2, as applicable, Ypsomed shall, upon the Parties good faith decision, either (a) [***] or, (b) [***]. In either case, [***] shall reimburse [***] for any applicable delivery charges. AMAG shall not request an [***] as set out under option (a) above, if the amount of defective Components is [***] as set forth in Appendix 4.

10.2 In the event the Parties are unable to agree as to whether or not a Component Set fails Initial Inspection under Section 9.1, has a Hidden Defect under Section 9.2, or complies with the product warranty set out in Section 11.1, the Parties shall select an independent laboratory which shall test such Component Set lot or Component Sets to determine whether such Component Set(s) fails Initial Inspection under Section 9.1, has a Hidden Defect under Section 9.2, or complies with the product warranty set out in Section 11.1. The findings of such laboratory shall be binding. [***] upon such laboratory testing shall pay the costs invoiced by such laboratory. During any period that the Parties are in dispute regarding the conformity of the Component Sets, Ypsomed shall, if requested by AMAG, replace such quantity of Component Sets. If the laboratory determines the Component Set(s) fail Initial Inspection under Section 9.1, has a Hidden Defect under Section 9.2, or does not comply with the product warranty set out in Section 11.1, then AMAG shall be entitled to the remedies set out in Section 10.1. If the laboratory determines the Component Set(s) passes Initial Inspection under Section 9.1, does not have a Hidden Defect under Section 9.2, or complies with the product warranty set out in Section 11.1, then AMAG shall pay for both the original shipment of Component Sets and the replacement shipment of Component Sets following such determination.

11. Representations and Warranties by Ypsomed

11.1 **Product Warranty**. Subject to Section 11.2, Ypsomed hereby represents and warrants to AMAG that the Component Sets delivered by Ypsomed to AMAG hereunder (a) will have been manufactured in accordance with this Agreement, the Quality Agreement and Applicable Laws, including, without limitation, cGMP in effect at the time of manufacture, (b) will, as of the date of Delivery, conform to the Specifications in effect at the time of manufacture, and (c) will not be adulterated

within the meaning of the U.S. Federal Food, Drug and Cosmetic Act, or any other law in the Territory.

11.2 **Warranty Limitation**. The warranty under Section 11.1 and AMAG's remedies under Section 10 shall not apply to, and shall be void in respect to (a) Components that have been modified or altered in any manner by anyone other than Ypsomed or its Affiliates or designees or authorized by Ypsomed, except that activities carried out by AMAG or its designees in the final assembly of a Component Set into a Bremelanotide Device in accordance with the applicable specification, including the Specifications, shall not be considered modified or altered under this Section 11.2(a), or (b) defects caused by anyone other than Ypsomed or its Affiliates or designees or authorized by Ypsomed (i) by the use or operation of the Component Sets in an application or environment other than that intended or recommended for the Component Sets and/or the Bremelanotide Devices (as further detailed in the Specifications or other separate documents such as the Bremelanotide Device IFU); ii) by accident, negligence, misuse or other causes other than the uses covered by this Agreement; or (iii) by packaging, transport, warehousing, storage or handling of the Component Sets, in any manner inconsistent with this Agreement, including, without limitation, the Specifications. Ypsomed expressly excludes any liability for instructions for use for the Component Sets or Bremelanotide Devices respectively.

11. 3 **Authority & Approvals.** Ypsomed represent and warrants that (a) it has full power and authority, and has taken all necessary actions and has obtained all necessary statutory authorizations, licenses and approvals required, to execute and perform this Agreement; and (b) its entry into this Agreement and its performance of its obligations under this Agreement do not, and will not, breach any agreements (to which it is party) with any third party.

11.4 **Regulatory Violations**. Ypsomed represents and warrants that it and its employees, agents, officers and directors have not been debarred, disqualified or convicted of a crime for which one can be debarred under Article 306 of the FDCA, 21 U.S.C. §335a(a) or (b), or any equivalent foreign or local law, rule or regulation. In the event that Ypsomed or any of its employees, agents, officers and directors becomes so debarred, disqualified or convicted, Ypsomed agrees to notify AMAG thereof immediately, and AMAG shall have the right to terminate this Agreement pursuant to Section 21.2. Ypsomed further represents and warrants that it has not and shall not knowingly use or employ in any capacity related to any activities under this Agreement any individual, corporation, partnership, or association which has been debarred, disqualified or convicted of a crime for which one can be debarred under Article 306 of the FDCA, 21 U.S.C. §335a(a) or (b), or any equivalent foreign or local law, rule or regulation. In the event that Ypsomed becomes aware of or receives notice of the debarment, disqualification or conviction of any such individual, corporation, partnership, or association providing services to it which relate to any activities under this Agreement, Ypsomed agrees to notify AMAG immediately thereof, and AMAG shall have the right to terminate this Agreement pursuant to Section 21.2.

12. Representations and Warranties by AMAG

12.1 AMAG warrants that, following Delivery to AMAG or its designee, all Component Sets shall be transported, warehoused, stored, processed, handled and marketed by AMAG or its designees in accordance with this Agreement, including the Specifications, and all Applicable Laws. AMAG further warrants that it will not knowingly put on the market any Component Sets or Bremelanotide Device with known defects nor shall AMAG knowingly put on the market any Component Sets or

Bremelanotide Device except subject to and in accordance with the applicable specifications, including the Specifications and Authorizations.

12.2 AMAG warrants that all advertising and promotional materials as well as user manuals and other information, instructions and directions of use relating to safety and risk issues, use, transport, handling, and storage of the Bremelanotide Device shall comply with the applicable specifications, and all applicable laws, rules, and regulations in the Territory.12.3 AMAG warrants that it will not market, offer to sell or sell any Bremelanotide Device in any country unless and until it has all the necessary Authorizations from the relevant regulatory agency in such country that are required to market, offer to sell and sell the Bremelanotide Device. Ypsomed will support AMAG in obtaining such Authorizations in accordance with Section 14 and as set out in the Quality Agreement.

12.4 **Authority & Approvals.** AMAG represent and warrants that (a) it has full power and authority, and has taken all necessary actions and has obtained all necessary statutory authorizations, licenses and approvals required, to execute and perform this Agreement; and (b) its entry into this Agreement and its performance of its obligations under this Agreement do not, and will not, breach any agreements (to which it is party) with any third party.

12.5 **Regulatory Violations**. AMAG represents and warrants that is has not been debarred under Article 306 of the FDCA, 21 U.S.C. §335a(a) or (b), or any equivalent foreign or local law, rule or regulation. In the event that AMAG becomes debarred, AMAG agrees to notify Ypsomed thereof immediately, and Ypsomed shall have the right to terminate this Agreement pursuant to Section 21.2. AMAG further represents and warrants that it has not and shall not knowingly use or employ in any capacity related to any activities under this Agreement any individual, corporation, partnership, or association which has been debarred under Article 306 of the FDCA, 21 U.S.C. §335a(a) or (b), or any equivalent foreign or local law, rule or regulation. In the event that Ypsomed becomes aware of or receives notice of the debarment of any such individual, corporation, partnership, or association providing services to it which relate to any activities under this Agreement, AMAG agrees to notify the Ypsomed immediately thereof, and Ypsomed shall have the right to terminate this Agreement pursuant to Section 21.2.

13. Quality Management System

13.1 On or about the date hereof the Parties shall enter into a Quality Agreement covering the Components and Component Sets. The Parties shall review the Quality Agreement and shall modify same from time to time as detailed in the Quality Agreement as necessary through a written amendment to the Quality Agreement signed by an authorized representative on behalf of each of the Parties. The Parties shall perform the quality control and quality assurance testing specified in this Section 13, the Quality Agreement, the Specifications and Applicable Laws.

13.2 Ypsomed shall (i) maintain a quality management system, (ii) manufacture the Component Sets and (iii) generate and maintain the compilation of records of the manufacturing, testing, processing, packaging, labeling, and storage of the Component Sets in accordance with the Quality Agreement. Reference is made to Section 24.7 for the language of such records.

13.3 Ypsomed will participate in and support AMAG in all required actions in respect of AMAG's medical device vigilance systems, including, without limitation, support in

respect of initial reporting and corrective action, as set out in the Quality Agreement or required by Applicable Law.

13.4 In accordance with the Quality Agreement, Ypsomed shall allow AMAG (and, if requested by AMAG, its notified body) to audit Ypsomed's manufacturing facilities in order to assure compliance with this Agreement and the Quality Agreement.

13.5 Unless otherwise indicated, [***] incurred in respect of Audits pursuant to Section 13.4. All information obtained by AMAG in any Audit (including, without limitation, the findings and results related thereto but excluding all Confidential Information of AMAG) shall be deemed to be Ypsomed's Confidential Information that may not be shared with any third parties, except as otherwise permitted under this Agreement (which permitted uses include, for clarity, use in regulatory filings for Authorizations, provided however that AMAG shall not be authorized to list patents of Ypsomed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) without the prior written consent of Ypsomed) or unless compulsory under Applicable Law.

14. Authorizations

14.1 AMAG shall obtain and maintain all Authorizations for the Bremelanotide Device and shall be the sole owner of such Authorizations in the Territory. The costs for such applications and Authorizations shall be borne by [***]. Subject to Section 14.3, as between the Parties, AMAG shall be responsible for all communications with Authorities regarding such Authorizations.

14.2 For the purposes of Sections 14.3 and 14.4, AMAG shall use reasonable efforts to notify Ypsomed in a timely manner about its application schedule for Authorizations and any updates thereto. AMAG shall use reasonable efforts to regularly inform Ypsomed about the expected times for obtaining the Authorizations and notify Ypsomed in writing about any Authorizations obtained.

14.3 Ypsomed shall use reasonable efforts to provide AMAG or, at AMAG's request, Authorities in the Territory with any data and information (in English) relating to Ypsomed's performance under this Agreement, which is necessary to apply for and/or maintain Authorizations in the Territory.

14.4 Ypsomed agrees to cooperate with any inspection of Ypsomed's facilities by Authorities, including any regulatory inspection required for AMAG to apply for and/or maintain Authorizations, in accordance with the Quality Agreement.

14.5 Any provision in this Agreement, including, without limitation, in the Quality Agreement, giving AMAG the right to access, control, check or receive documents from Ypsomed or to visit or audit Ypsomed's premises, shall be interpreted as covering all documents and information relevant to the Components but excluding trade, operating and/or business secrets of Ypsomed and/or its subcontractors. If documents or information containing such trade, operating and business secrets are required for (i) AMAG's certification by an Authority, (ii) applying for and/or maintaining Authorizations in the Territory, (iii) risk evaluation by an Authority or (iv) market surveillance by an Authority, the document or information will be disclosed only to the relevant Authority. Ypsomed shall inform AMAG of any information directly submitted to Authorities, and Ypsomed shall be responsible for any updates and annual reports required by such Authorities in respect of such information.

14.6 [***] shall [***] in respect of Ypsomed's activities of providing data and information as set out in Section 14.3, Section 14.4 and Section 14.5, provided such costs are administrative costs of Ypsomed. To the extent such costs relate to the Authorizations and are not administrative costs (e.g., costs for the undertaking of further technical studies, tests or experiments, costs for translation of or costs for compiling additional documents), [***] shall pay the respective costs, provided [***] supplies reasonable documentation substantiating such costs, except as otherwise agreed upon in writing. For one (1) regulatory inspection related to the Authorizations every [***] pursuant to Section 14.4, [***] shall bear its own costs. [***] shall pay the reasonable costs incurred by [***] for regulatory inspections in excess of one (1) every [***] related to the Authorizations, provided [***] supplies reasonable documentation substantiating such costs, except if such inspection is for-cause.

15. Patient Complaints and Recalls

15.1 The process for resolving complaints, adverse events, and inquiries related to the Bremelanotide Device shall be in accordance with the Quality Agreement. As between the Parties, AMAG shall have the sole responsibility for resolving patient questions or complaints related to the Bremelanotide Device. Ypsomed shall refer any patient questions and complaints (including safety and efficacy inquiries, quality complaints and adverse event reports) that it receives concerning the Bremelanotide Device to AMAG (together with all available evidence and other information relating thereto) in accordance with the Quality Agreement. Ypsomed shall not take any further action in connection with any such patient questions or complaints without the consent of AMAG, but shall cooperate in the investigation and closure of any such questions or complaints at the request of AMAG. Such assistance shall include follow-up investigations, including testing according to Ypsomed's SOP and complaint handling proceedings. In addition, Ypsomed shall provide AMAG with all information to enable AMAG to respond properly to patient questions or complaints relating to the Components Sets as provided in the Quality Agreement.

15.2 As between the Parties, AMAG shall have the sole responsibility as to whether to institute a recall or withdrawal of Bremelanotide Devices (whether required by an Authority or instituted by AMAG for any reason). Ypsomed shall support AMAG as set out in the Quality Agreement. If AMAG plans a recall or withdrawal of the Bremelanotide Device, AMAG shall notify Ypsomed promptly of the details regarding such recall or withdrawal, including, without limitation, providing copies of all relevant documentation concerning such recall or withdrawal. As far as the Components are concerned, Ypsomed shall cooperate with AMAG in any such recall and AMAG shall reasonably consider Ypsomed's input in respect to the Components. Ypsomed shall provide such information in respect of Ypsomed's performance under this Agreement as AMAG reasonably requests or which is necessary according to Applicable Laws. All regulatory contacts that are made and all activities concerning such recall will be initiated and coordinated by AMAG with Ypsomed's involvement and assistance, as such involvement and assistance is reasonably requested by AMAG. .

15.3 Ypsomed shall indemnify AMAG and bear the expense and costs, including replacements costs but not including loss of profit, resulting from a recall or withdrawal of Bremelanotide Device to the extent caused by a failure of the Components to comply with the product warranty set out in Section 11.1.

16. Intellectual Property Rights

16.1 Any and all Intellectual Property Rights in existence prior to the Effective Date or developed during the period of this Agreement but otherwise than in the course of performance of obligations under this Agreement shall, as between the Parties, remain the sole and exclusive property of the Party that brings such rights to this Agreement.

16.2 Ypsomed shall be the sole and exclusive owner of [***] ("New Ypsomed Intellectual Property Rights"). AMAG agrees to assign and hereby assigns all of its rights, including all patent rights, to such New Ypsomed Intellectual Property Rights to Ypsomed, and such New Ypsomed Intellectual Property Rights shall be included in the license in Section 16.4. Ypsomed shall be solely entitled to legally protect any such New Ypsomed Intellectual Property Rights and shall bear all related costs.

16.3 AMAG shall be the sole and exclusive owner of [***] ("New AMAG Intellectual Property Rights"). Ypsomed agrees to assign and hereby assigns all of its rights, including all patent rights, to such New AMAG Intellectual Property Rights to AMAG. AMAG shall be solely entitled to legally protect any such New AMAG Intellectual Property Rights and shall bear all related costs.

16.4 Ypsomed grants to AMAG a royalty-free, fully paid-up, irrevocable (during the term of this Agreement), sublicensable and non-exclusive license in respect of the Ypsomed Intellectual Property Rights and New Ypsomed Intellectual Property Rights to the extent required for AMAG to final assemble and pack, use, sell, offer for sale, distribute, import and export the Components, Component Sets and Bremelanotide Device. This limited license shall only survive an expiration or termination of this Agreement to the extent that a permitted use set out hereunder outlasts the expiration or termination of this Agreements. For the avoidance of doubt, the license shall survive expiration or termination of this Agreement with respect to any and all Component Sets ordered or purchased as of the date of expiration or termination until such time as the resulting Bremelanotide Devices have been sold or have expired. The license shall not include the right to manufacture or have manufactured the Components.

16.5 Each Party shall cooperate with the other in completing any patent applications or obtaining any other patent rights relating to Intellectual Property Rights created or developed under this Agreement, including executing and delivering any instrument required to assign or transfer such Intellectual Property Rights to the other Party in accordance with Sections 16.2 or 16.3.

16.6 Ypsomed has established a continuous standard patent surveillance in the EU, USA and Switzerland concerning the YpsoMate. Under this Agreement Ypsomed shall continue to undertake its continuous standard patent surveillance concerning the YpsoMate.

In the event that Ypsomed becomes aware of any third party patent rights (granted patents) that may reasonably adversely impact AMAG's use of the Components in accordance with this Agreement, Ypsomed shall notify AMAG thereof in writing without delay.

Ypsomed represents and warrants that [***] it has not received any claims from a third party that the YpsoMate or the performance of the activities under this Agreement infringe or misappropriate the rights of any third party Intellectual Property Rights and according to Ypsomed's assessment (of infringement and validity) and good faith belief, [***], the use of the Components and Component Sets in accordance with this Agreement does not infringe or misappropriate any valid and enforceable issued third party patent. If Ypsomed becomes aware of any third party claims of patent infringement or misappropriation (e.g., by receiving a cease and desist letter) after the Effective Date, Ypsomed shall promptly notify AMAG thereof in writing.

16.7 If either Party becomes aware of any claim or action by a third party claiming that the YpsoMate or the Component Sets infringes or misappropriates a third party patent (in particular upon receipt of a corresponding letter from such third party) (each a "**Third Party Action**"), such Party shall promptly inform the other Party of such Third Party Action.

16.8 The defense against a Third Party Action shall be ruled as follows:

a) If the Third Party Action is directed against Ypsomed for alleged infringement of a third party patent by the YpsoMate, Ypsomed shall defend at its sole cost the Third Party Action directed against the YpsoMate through counsel of its choice. Ypsomed shall reasonably update and inform AMAG on its defense strategy and the status of any Third Party Action under this Section 16.8(a).

b) If the Third Party Action is [***] then AMAG shall have the right to defend such Third Party Action [***]. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action. The non-controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. In the event that AMAG is enjoined from selling the Bremelanotide Device as a result of such Third Party Action, [***].

c) For Third Party Actions under Section 16.8 (b), the Party conducting the defense to such Third Party Action shall (i) take all reasonable steps to prevent judgment by fault or by default being granted in favor of the third party; (ii) ensure that the other Party is given the right to conduct proper consultations with the third party in relation to the claim or potential claim; (iii) if appropriate and practicable, allow the other party to join in the defense (including, without limitation, settlement, litigation or appeal) of any claim; and (iv) not, without the prior written consent of the other Party, settle or compromise any claim or consent to the entry of any judgment that imposes any liability or obligation upon such Party.

16.9 In the event it is established that the Components infringe a third party patent or if the Parties agree to settle any claim or consent to the entry of any judgment that prevents Ypsomed to continue to manufacture and supply the Components to AMAG, the Parties shall mutually agree on the strategy to be followed which may contain one of the following actions: (i) Ypsomed at its own cost shall redesign the Components to avoid the infringement, or (ii) Ypsomed at its own cost shall procure to obtain a license from such third party, [***]. If the Parties cannot agree on either of such actions, or if such actions are not possible or successful, the Parties agree to discuss in good faith alternative solutions, whereas in case such alternative solutions are not possible or successful, the Parties agree to consensually terminate this Agreement.

16.10 If any Ypsomed Intellectual Property Right licensed to AMAG under this Agreement is infringed and/or misappropriated by a third party (the " **Infringed Intellectual Property**") the Party first having knowledge of such infringement/misappropriation shall promptly notify the other Party in writing.

17. Disclaimer

Except as expressly set out in this Agreement, neither Party makes any warranties in respect of its activities under this Agreement, express or implied, including, without limitation, any implied warranty of merchantability or fitness for a particular purpose.

18. Indemnity and Insurance

18.1 Ypsomed agrees to indemnify, defend and hold harmless AMAG, its Affiliates and its and their respective officers, directors, employees, subcontractors, and agents (collectively, the "**AMAG Indemnitees**") against any and all losses, damages, liabilities or expenses (including reasonable attorney's fees and other costs of defense) (collectively, "**Losses**") in connection with any and all actions, suits, claims or demands that are brought or instituted against any AMAG Indemnitee by any third party to the extent they arise out of (a) any breach of Ypsomed's representations, warranties or obligations set out in this Agreement, including but not limited to the ones set out in Sections 11, 16.6 and 16.7, (b) any Ypsomed Indemnitees' gross negligence or willful misconduct in performing obligations under this Agreement, (c) a recall or withdrawal of Bremelanotide Device in accordance with Section 15.3, or (d) [***] except, in each case, to the extent that such Losses result from an action for which AMAG has an obligation to indemnify Ypsomed under Section 18.2(a), (b) or (c).
[***].

18.2 AMAG agrees to indemnify, defend and hold harmless Ypsomed, its Affiliates and its and their respective officers, directors, employees, subcontractors, and agents (collectively, the "**Ypsomed Indemnitees**") against any and all Losses in connection with any and all actions, suits, claims or demands that are brought or instituted against any Ypsomed Indemnitee by any third party to the extent they arise out of (a) the use of the Component Sets, (b) any breach of AMAG's representations, warranties or obligations set out in this Agreement, (c) any AMAG Indemnitee's gross negligence or willful misconduct in performing obligations under this Agreement, or (d) any claim alleging that the manufacture, use, offer for sale, sale, import or export of Bremelanotide infringes any Intellectual Property Rights of a third party, except, in each case, to the extent that such Losses result from an action for which Ypsomed has an obligation to indemnify AMAG under Section 18.1(a), (b) or (c).

18.3 Each Party agrees that if it is notified by a third party of any claim or potential claim that may give rise to a right of indemnification pursuant to Section 18.1 or Section 18.2, it shall

a) forthwith inform the other Party of such claim or potential claim;

b) take all reasonable steps to prevent judgment by fault or by default being granted in favor of the third party;

c) ensure that the other Party is given the right to conduct proper consultations with the third party in relation to the claim or potential claim;

d) if appropriate, allow the other party to join in the defense (including, without limitation, settlement, litigation or appeal) of any claim; and

e) not, without the prior written consent of the other Party, settle or compromise any claim, or consent to the entry of any judgment that imposes any liability or obligation upon such Party.

18.4 Both Parties shall obtain and maintain for the duration of this Agreement and a period of [***] thereafter comprehensive liability insurance and other insurance all in amounts and with coverage as required by the jurisdictions in which they operate or as necessary to cover their obligations pursuant to this Agreement. Each Party shall, within [***] of any request from the other Party, provide a copy or extract of its certificate of insurance to the other Party evidencing compliance with this Section.

19. Limitation of Liability

19.1 To the extent permitted by the applicable law, neither Party shall be liable to the other Party or to any third party, under this Agreement, in contract, tort (including negligence) or otherwise howsoever, and whatever the cause thereof, for lost profits, goodwill, the cost of procurement of substitute goods, the cost of Bremelanotide or for any consequential or indirect damages, provided, however that such limitation shall not apply with respect to any claim arising from (a) the gross negligence or willful misconduct of either Party, or (b) a breach of the confidentiality provisions of Section 20. This limitation shall apply even where a Party has been advised of the possibility of such damage and notwithstanding the failure of the essential purpose of any limited remedy stated herein.

19.2 To the extent permitted by applicable laws and subject to the provisions of this Section 19.2, either Party's liability under this Agreement in any calendar year shall be limited to the greater of (a) [***]) and (b) the total charges paid by AMAG to Ypsomed under this Agreement during the [***] period preceding the event that gave rise to the liability, provided, however that Ypsomed's liability over such calendar year shall in any event be limited to [***]. Such limitation shall not apply with respect to any claim arising from (a) the gross negligence or willful misconduct of either Party, or (b) a breach of the confidentiality provisions of Section 20.

It is hereby clarified that [***] own costs for defending a Third Party Action pursuant to Section 16.8 (a) or 16.8 (b) [***], shall not be considered as "liability" for the purpose of calculating [***] liability limit pursuant to this Section 19.2.

19.3 Each Party shall be obliged to mitigate damages.

20. Confidentiality

20.1 It is understood between the Parties that the existing secrecy undertakings as stipulated in the Confidentiality Agreement have been and shall remain in force with respect to information exchanged thereunder.

20.2 For purposes of this Agreement, "**Confidential Information**" includes all information furnished by or on behalf of a Party (the " **Disclosing Party**"), its Affiliates or any of its or their respective Representatives (as defined below), to the other Party (the "**Receiving Party**"), its Affiliates or any of its or their respective Representatives, in respect of this Agreement or any performance hereunder, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other Party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, ideas, processes, formulas, samples, compounds, extracts, inventions and any other intellectual property (whether or not patented), analyses and compilations, business, technical and financial information and other materials prepared by either Party, their respective Affiliates, or any of its or their respective representatives, containing or based in whole or in part on any information furnished by the Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence of this Agreement and its terms.

20.3 The Receiving Party shall maintain all Confidential Information in trust and confidence and shall not disclose or divulge or use any Confidential Information for any purpose other than the performance of its obligations under this Agreement without the prior written consent of the Disclosing Party.

20.4 The Receiving Party may disclose Confidential Information to its officers, directors, employees, agents, independent, consultants, attorneys or accountants (collectively "**Representatives**") only on a need to know basis; provided that (a) such Representatives are bound by written agreements to maintain in confidence and not use the Confidential Information under terms at least as restrictive as the terms of this Agreement, and (b) the Receiving Party shall be liable for any breach by its Representatives of any obligations hereunder.

20.5 The foregoing obligations of confidentiality shall not apply to Confidential Information that the Receiving Party can prove by competent written proof:

a) was known to the Receiving Party prior to its receipt from the Disclosing Party, or

b) is publicly available prior to receipt from the Disclosing Party or subsequently becomes publicly available through no fault of the Receiving Party, or

c) is obtained by the Receiving Party from a third party who is not under an obligation of confidentiality and has a lawful right to make such disclosures, or

d) is independently developed by or for the Receiving Party without use of the Disclosing Party's confidential information.

20.6 The Receiving Party may make disclosures required by an order of a governmental agency, legislative body or court of competent jurisdiction, provided that the Receiving Party: (i) provides the Disclosing Party with immediate written notice of such requirement, (ii) cooperates with the Disclosing Party at the Disclosing Party's expense in connection with the Disclosing Party's reasonable and lawful actions to obtain confidential treatment for such Confidential Information, and (iii) limits such disclosure of Confidential Information to the fullest extent permitted under applicable law.

20.7 The confidentiality and non-use obligations imposed by this Agreement shall expire with respect to any particular item of a Disclosing Party's Confidential Information on the [***] anniversary of the date of disclosure of such Confidential Information.

21. Term and Termination

21.1 The term of this Agreement shall commence on the Effective Date and, unless terminated under Sections 21.2 through 21.6, this Agreement shall continue in full force and effect until [***] ("**Initial Term**"). This Agreement shall be automatically renewed for successive [***] year periods (each a "**Subsequent Term**" and, with the Initial Term, the "**Term**") unless either Party terminates this Agreement by [***] written notice to the other Party prior to the expiration of the Initial Term or any Subsequent

Term, as applicable. [***] before expiration of this Agreement, the Parties shall undertake to facilitate the phase out and wind down of the supply.

21.2 This Agreement may be terminated by either Party effective upon [***] written notice to the other Party in the event of material breach of this Agreement by the other Party, provided it has previously given written notice of such material breach and the breaching Party has failed to remedy such breach within [***] of receipt of such notice.

21.3 This Agreement may be terminated by either Party effective immediately upon written notice to the other Party (i) upon the institution by or against the other Party of insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of the other Party's debts, unless such other Party timely contests such proceedings, (ii) upon the other Party's making an arrangement for the benefit of creditors, or (iii) upon the other Party's dissolution or cessation of business.

21.4 This Agreement may be terminated by either Party effective upon [***] written notice to the other Party in the event of a change of control of the other Party if such controlling party is a competitor of the terminating Party. For the purposes of this Section 21.4, the term "**control**" shall have the same meaning as set out in Section 1 in respect of Affiliates.

21.5 This Agreement may be terminated by AMAG if the Bremelanotide Device does not receive FDA approval, provided AMAG notifies Ypsomed in writing with [***] notice that it wishes to terminate the Agreement.

21.6 This Agreement may be terminated by AMAG if AMAG is required to withdraw the Bremelanotide Device from the market for regulatory or health and safety reasons, provided AMAG notifies Ypsomed in writing with [***] notice that is wishes to terminate the Agreement.

22. Effects of Termination or Expiration

22.1 Upon termination by Ypsomed or receipt of notice of termination from AMAG, Ypsomed will as soon as reasonably practicable cease performance of the applicable activities in respect to the Component Sets and will take reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith.

22.2 Each Party shall return all documents and materials in its possession which contain confidential information of the other Party within [***] after termination or expiration of this Agreement, except for copies of information that may be routinely and automatically stored in the Party's computer backup and electronic communications systems. The receiving Party may retain one copy of documents and materials which contain the disclosing Party's confidential information for the purpose of verifying the receiving Party's compliance with its obligations under this Agreement or as required by Applicable Laws, but for no other purpose whatsoever.

22.3 Sections 1, 2, 4.4, 6, 9, 10, 11, 12, 13.2(iii), 13.3, 14.3, 14.4, 14.5, 14.6, 15, 16, 17, 18, 19, 20, 22, 24.1, 24.2, 24.4, 24.5, 24.6, 24.7, 25 and 26 shall survive termination or expiration of this Agreement.

22.4 In the event of termination of this Agreement by Ypsomed according to Section 21.2, 21.3 or 21.4, [***] shall (i) [***].

22.5 In the event of termination of this Agreement by AMAG according to 21.5 or 21.6, [***] shall (i) [***].

22.6 In the event of termination of this Agreement by [***] according to Sections 16.9, 21.2, 21.3 or 21.4, [***].

23. Force Majeure

Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses (except for payment obligations) on account of failure of performance by the defaulting Party if the failure is occasioned by war, strike, acts of terrorism, fire, acts of god, earthquake, flood, lockout, embargo, governmental acts or orders or restrictions or any other similar reason where failure to perform is beyond the reasonable control of and could not reasonably have been expected to occur by the defaulting Party and such Party has exerted all reasonable efforts to avoid or remedy such force majeure. Failure to obtain, or revocation of, one or more Authorizations shall not be considered an event of force majeure.

24. Miscellaneous

24.1 **Entire Agreement**. This Agreement, including its Appendices, together with the Confidentiality Agreement, set forth the entire agreement and understanding of the Parties in respect of the subject matter hereof, and supersedes all prior discussions, agreements and writings relating thereto.

24.2 **Independent Contractors**. The relationship of the Parties hereto is that of independent contractors. The Parties are not deemed to be agents or partners nor are they engaged in a joint venture for any purpose as a result of this Agreement or the transactions contemplated herein.

24.3 **Assignment.** Except as otherwise expressly provided herein, the Parties agree that their rights and obligations under this Agreement shall not be delegated, transferred or assigned to a third party without the prior written consent of the other Party; provided either Party may assign this Agreement or parts thereof to its Affiliates, without the other Party's consent. Subject to Section 21.4, either Party may assign this Agreement in its entirety, without the other Party's consent, to a successor to substantially all of the business or assets of the assigning Party. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and permitted assigns.

24.4 **Severability, Waiver**. In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement, or will leave the provision unreplaced by mutual consent. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable. The failure of a Party to enforce any provision of this Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce that provision or any other provision or right.

24.5 **Notices**. Any required notices hereunder shall be given in writing and sent by (a) facsimile or electronic mail transmission (receipt verified), (b) recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt

or (c) priority mail, postage prepaid, with written verification of receipt, in each case, to the address of the applicable Party below, or to such other address as such Party may substitute by written notice.

If to AMAG:
AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451
USA

Attention: VP, Technical Operations
Fax:

with a copy to:
Attention: General Counsel
Fax:

If to Ypsomed:

Ypsomed AG
Brunnmattstrasse 6
CH-3401 Burgdorf
Switzerland

Attention: General Counsel
Fax: +41 (34) 424 41 55

With a copy to:
Attention: Product and Account Manager AMAG

Either Party may change its address for communications by a notice to the other Party in accordance with the terms of this Section 24.5.

24.6 **No Use of Name**. Neither AMAG nor Ypsomed shall be permitted to use the name of the other Party in any publicity, advertising or public announcement concerning this Agreement or the subject matter hereof without the prior express written consent of the other Party except to the extent required by law. As soon as the Bremelanotide Device is in the market, Ypsomed shall be allowed to mention AMAG in its clients list and to show the Component Set (assembled with a syringe of placebo) in trade fairs, exhibitions and publications.

24.7 **English Language**. This Agreement has been prepared in the English language and the English language shall control its interpretation. All notices required or permitted to be given hereunder, and all written or other communications between the Parties regarding this Agreement or pursuant to this Agreement, shall be in the English language, unless otherwise stated herein. AMAG acknowledges that parts of the technical and quality documentation for the Component Sets and the documentation of Ypsomed's business activities are in the German language.

25. Arbitration and Governing Law

25.1 **Disputes**. The Parties will try to settle their differences amicably between themselves. If any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement, including the performance or alleged nonperformance of a Party of its obligations under this Agreement arises between the Parties (each a "**Dispute**"), a Party will, before initiating any proceedings pursuant to Section 6(c), notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within [***] of receipt of the written notice by the other Party, such dispute will be referred to an executive officer of AMAG and an executive officer of Ypsomed, or their designees, who will meet in person at least once and use their good faith efforts to resolve the Dispute within [***] after such referral.

25.2 **Arbitration**. If a Dispute is not resolved as provided in Section 25.1, whether before or after expiration or termination of these Terms and Conditions, the Parties hereby agree that such Dispute will be resolved by final and binding arbitration conducted in accordance with the [***]. The arbitration will be held in [***]. The governing law of this Agreement will govern any such proceedings. The arbitration will be conducted by a panel of three (3) arbitrators with significant experience in the pharmaceutical manufacturing industry, unless otherwise agreed by the Parties, appointed in accordance with applicable [***]. Any arbitration herewith will be conducted in the English language to the maximum extent possible. The arbitrators will be instructed not to award any punitive or special damages and will render a written decision no later than [***] following the selection of the arbitrators, including a basis for any damages awarded and a statement of how the damages were calculated. Any award will be promptly paid in U.S. dollars free of any tax, deduction or offset. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 6. With respect to money damages, nothing contained herein will be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages. Each Party will pay its legal fees and costs related to the arbitration (including witness and expert fees). Judgment on the award so rendered will be final and may be entered in any court having jurisdiction thereof.

25.3 Governing Law. This Agreement and any dispute arising therefrom shall be governed by and construed in accordance with the laws of [***], regardless of the conflict of laws principles of that or any other jurisdiction. The UN Convention on Contracts for the International Sale of Goods is not applicable to this Agreement.

25.4 Nothing in this Section 25 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, specific performance or other interim equitable relief, concerning a Dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

26. Securities Laws. The parties hereby acknowledge that AMAG is publicly traded on the NASDAQ National Market System under the symbol "AMAG" and Ypsomed is publicly traded on the Swiss Performance Index (SPI) of SIX Swiss Exchange. Further, each party is aware and will advise its Representatives who are informed of matters that are the subject of this Agreement, of the restrictions imposed by certain applicable securities laws on the purchase or sale of securities by any person who has received or had access material, nonpublic information concerning a company and on the communication of such information to any other person when it is reasonably foreseeable that such person is likely to purchase or sell such securities in reliance on such information.

In witness whereof, AMAG and Ypsomed have executed this Agreement in two originals, one for each Party, by their respective duly authorized representatives.

AMAG Pharmaceuticals, Inc.	
Date:	December 21, 2018
By:	/s/ William K. Heiden
Print Name:	William K. Heiden
Title:	President and CEO

Ypsomed AG	
Date:	January 25, 2019
By:	/s/ Ulrike Bauer
Print Name:	Ulrike Bauer
Title:	SVP Marketing and Sales Delivery Systems
By:	/s/ Frank Mengis
Print Name:	Frank Mengis
Title:	COO

Appendix 1
Specifications for Components

The Specifications for the Components are kept in the Design History File (DHF), which is maintained at Ypsomed's premises.

Appendix 2
Quality Agreement

Separate Document.

Appendix 3
Commercial Terms

1. Applicable Capacity & Contribution

1.1 Ypsomed will invest in the entire production infrastructure required to produce the Components, including high-cavity tooling and fully automatic assembly equipment.

Pursuant to the terms of the Industrialization Proposal, [***] partially financed the manufacturing capacity build-up through upfront payments as set out in the Industrialization Proposal.

1.2 AMAG and Ypsomed will determine the required manufacturing capacity that Ypsomed will reserve for AMAG based on AMAG's Long Range Forecast delivered by AMAG to Ypsomed in accordance with Section 7.1 of the Supply Agreement. It is agreed between the Parties that the applicable manufacturing capacity per calendar year ("**Applicable Capacity**") will be determined in accordance with this Section 1.2. The initial Applicable Capacity is [***] Component Sets. The Applicable Capacity may be adjusted, from time to time upon either Party's written request, based on the Long Range Forecast. In the event AMAG requests an increase in the Applicable Capacity that requires Ypsomed to invest in additional production infrastructure, such change shall be possible provided AMAG notifies Ypsomed at least [***] prior to such requested increase. In the event AMAG or Ypsomed in good faith requests a decrease in the Applicable Capacity, such change shall be possible provided that the Party requesting such decrease notifies the other Party at least [***] prior to such requested decrease. Each change of the Applicable Capacity shall be agreed upon by the Parties in good faith. In the event AMAG's capacity demand according to the Long Range Forecast exceeds [***] Component Sets per calendar year, the parties shall negotiate in good faith the terms upon which Ypsomed will expand its manufacturing capacity to accommodate AMAG's increased capacity demand. In the event AMAG's capacity demand according to the Long Range Forecast exceeds [***] Component Sets per calendar year (i.e., a commitment for Applicable Capacity above [***] but not more than [***] Component Sets) AMAG shall pay Ypsomed a capacity contribution fee of [***]) as follows upon receipt of an invoice from Ypsomed:

Payment Milestones (Contribution for Applicable Capacity from [***] **to** [***] **Component Sets)**	**Amount in** [***]
[***] prior to the planned change of Applicable Capacity (i.e. date of request for additional capacity above [***] Component Sets per calendar year)	[***]
[***] prior to the planned change of Applicable Capacity (i.e. [***] after date of request for additional capacity above [***] Component Sets per calendar year)	[***]
[***] prior to the planned change of Applicable Capacity (i.e. [***] after date of request for additional capacity above [***] Component Sets per calendar year)	[***]
Total	[***]

2. Minimum Purchase Quantity

In accordance with Section 4.8 of the Supply Agreement, beginning in 2019 AMAG shall purchase at least the Annual Minimum Quantity of Component Sets in each calendar year during the Term as set forth below. For the purpose of determining whether AMAG is in compliance with Section 4.8 of the Agreement, a Component Set is considered "purchased" as of the agreed Delivery Date in the respective Purchase Order, provided however that such ordered Component Sets will have been duly purchased and paid by AMAG (during such calendar year or, as applicable, at a later stage in accordance with the terms of this Agreement).

Units	Minimum Purchase Quantity
Per Purchase Order	[***] (the "**Minimum Batch Size**")
Initial Term	[***] Component Sets per each calendar year during the Initial Term beginning in [***] (the "**Annual Minimum Quantity**")
Subsequent Term(s)	The Annual Minimum Quantity for the Subsequent Term(s) shall be determined and mutually agreed upon by the Parties prior to the end of the Initial Term or of each Subsequent Term, as applicable. If the Parties cannot agree on the Annual Minimum Quantity for a Subsequent Term prior to beginning of such Subsequent Term, AMAG shall be obligated to purchase, in each calendar year during the Subsequent Term, no less than the Annual Minimum Quantity for the last full calendar year

3. Purchase Price

The invoiced Purchase Price for Component Sets applied to all invoices during a calendar year will be determined based on number of Component Sets for the respective calendar year as set forth in the Binding Forecast and as determined according to the following Pricing Tiers:

Pricing Tiers

Annual Quantity of Component Sets	**Unit Price per Component Set in** [***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The Purchase Price includes the costs for bulk packaging (bulk packaging as set out in **Appendix 2**).

The effective Unit Price per Component Set shall be determined based on the total number of Component Sets ordered by AMAG for the respective calendar year accordance with Section 7.3, provided however that such ordered Component Sets will have been duly purchased and paid by AMAG (during such calendar year or, as applicable, at a later stage in accordance with the terms of this Agreement).

Accordingly, within [***] after the end of each calendar year during the Term, Ypsomed shall calculate the total amount of ordered Component Sets duly purchased and paid by AMAG and shall perform a "**True-Up**" reconciliation and shall provide AMAG with a written report of such reconciliation. If the True-Up report shows that a difference in the number of Component Sets purchased by AMAG compared to the pricing tier serving as basis for the invoiced Purchase Price in such calendar year results in either an underpayment or an overpayment between the Parties, the Party owing payment to the other Party shall pay the amount of the difference to the other Party within [***] of the date of delivery of such True-Up report.

4. Invoicing

Ypsomed shall submit an invoice to AMAG upon each Delivery of Component Sets. The term of payment is [***] from the date of invoice.

5. Delivery

5.1 Ypsomed shall deliver the Component Sets in accordance with Section 8 of the Agreement and the shipping procedures set out in the Specifications.

5.2 All Component Sets shall be delivered to AMAG FCA Ypsomed's manufacturing facility (Incoterms 2010).

Appendix 4
Price Change Order

Price Change Order – [*insert number*]

Dated: [***insert date****]*

This is a Price Change Order of the purposes of Supply Agreement between **Ypsomed AG** and **AMAG Pharmaceuticals, Inc.** dated _____[*insert date*] (the "**Agreement**").

Terms used but not defined in this Price Change Order shall have the meaning given to them in the Agreement.

Effective Date: Day, Month, Year
End Date: Day, Month, Year

Current Purchase Price: $

Revised Purchase Price: $

New Total Cost (if applicable): $

The following reasons have caused the Purchase Price to change (increase or decrease):

1.

EXECUTED as an **AGREEMENT**

Signed by **YPSOMED AG**	Signed for and on behalf of **AMAG PHARMACEUTICALS, INC.**
_____ Signature	_____ Signature
_____ Name	_____ Name
_____ Title	_____ Title
_____ Date	_____ Date

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	State of Incorporation	Name Under Which Subsidiary Does Business
RhoMed Incorporated	New Mexico	RhoMed Incorporated

Exhibit 23

Consent of Independent Registered Public Accounting Firm

The Board of Directors

Palatin Technologies, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-33569, 333-56605, 333-64951, 333-72873, 333-84421, 333-52024, 333-54918, 333-74990, 333-100469, 333-101764, 333-104370, 333-112908, 333-128585, 333-132369, 333-140648, 333-146392, 333-174251, 333-183837, 333-185113, 333-201821, 333-206003, 333-206047 and 333-226905) on Form S-3 and in the registration statements (Nos. 333-57079, 333-83876, 333-128854, 333-149093, 333-163158, 333-174257, 333-191467, 333-206009, 333-214618, 333-221554 and 333-227354) on Form S-8 of Palatin Technologies, Inc. of our report dated September 25, 2020, with respect to the consolidated balance sheets of Palatin Technologies, Inc. and subsidiary as of June 30, 2020 and 2019, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity (deficiency), and cash flows for each of the years in the three-year period ended June 30, 2020, and the related notes (collectively, the consolidated financial statements), which report appears in the June 30, 2020 annual report on Form 10-K of Palatin Technologies, Inc. Our report on the consolidated financial statements refers to changes in accounting for revenue and leases.

/s/ KPMG LLP

Philadelphia, Pennsylvania
September 25, 2020

Certification of Chief Executive Officer

I, Carl Spana, certify that:

1. I have reviewed this Annual Report on Form 10-K of Palatin Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 25, 2020

/s/ Carl Spana
Carl Spana, President and Chief Executive Officer

Certification of Chief Financial Officer

I, Stephen T. Wills, certify that:

1. I have reviewed this Annual Report on Form 10-K of Palatin Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 25, 2020

/s/ Stephen T. Wills
Stephen T. Wills, Executive Vice President, Chief
Financial Officer and Chief Operating Officer

EXHIBIT 32.1

Certification of Principal Executive Officer
Pursuant to 18 U.S.C. Section 1350
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Carl Spana, President and Chief Executive Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the Annual Report on Form 10-K for the year ended June 30, 2020 of Palatin Technologies, Inc. (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: September 25, 2020

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

EXHIBIT 32.2

Certification of Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Stephen T. Wills, Executive Vice President, Chief Financial Officer and Chief Operating Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the Annual Report on Form 10-K for the year ended June 30, 2020 of Palatin Technologies, Inc. (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: September 25, 2020

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