PEPLIN INC
Form 10-K
September 28, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2009

OR

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

Commission File Number 000-53410

Peplin, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-0641830**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
6475 Christie Avenue Emeryville, California	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

(510) 653-9700

(Registrant s Telephone Number, Including Area Code)

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

Securities registered pursuant to section 12(g) of the Act:

Common Stock, par value $0.001 per share

(Title of Class)

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

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 þ

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 twelve months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

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

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

Aggregate market value of registrant s common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant s CHESS Depositary Interest, which represents 1/20 of a share of registrant s common stock, on September 25, 2009 as reported by the Australian Securities Exchange on that date: A$13,757,153.

As of September 18, 2009, there were 15,371,121 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s amendment to this Form 10-K to be filed with the SEC not later than October 28, 2009 are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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Forward Looking Statements

This Annual Report on Form 10-K, or Form 10-K, contains forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and management s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- completing the merger of a wholly owned subsidiary of LEO Pharma A/S (LEO) with and into Peplin, with Peplin surviving the merger as a wholly owned subsidiary of LEO;
- our business and scientific strategies;
- the progress of our product development programs, including our clinical trials;
- our expectations with respect to regulatory submissions and approvals;
- our expectations with respect to corporate collaborations;
- our estimates regarding our research and development expenses;
- the protection of our intellectual property;
- our estimates regarding our capital requirements, the sufficiency of our cash resources and our need for additional financing;
- general economic and business conditions, both nationally and in our markets;
- our ability to manage our growth and development;
- our ability to attract and retain key management and scientific personnel; and
- existing and future regulations that affect our business.

In addition, in this Form 10-K, the words believe, may, will, estimate, continue, anticipate, intend, ex predict, potential, and similar expressions, as they relate to our business and our management, are intended to identify forward-looking statements. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this Form 10-K may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the cautionary statements in this Form 10-K, particularly in the section entitled Item 1A. Risk Factors. However, new factors emerge from time to time and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, any cause actual results to differ materially from those contained in any forward-looking statements.

Forward-looking statements speak only as of the date the statements are made. You should not place undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference

should be drawn that we will make additional updates with respect to those or other forward-looking statements.

PART I

Item 1. *Business*

Overview

We are a development stage specialty pharmaceutical company focused on advancing and commercializing innovative medical dermatology products. We are currently developing PEP005 (ingenol mebutate), or PEP005, a novel compound derived from *Euphorbia peplus*, or *E. peplus*, a rapidly growing, readily-available plant, commonly referred to as petty spurge or radium weed. The sap of *E. peplus* has a

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long history of traditional use for a variety of conditions, including the topical self-treatment of various skin disorders, such as skin cancer and pre-cancerous skin lesions.

Our lead product candidate, currently progressing through Phase 3 clinical trials, is a patient-applied topical gel containing PEP005, a compound the use of which we have patented for the treatment of actinic keratosis, or AK. AK is generally considered the most common pre-cancerous skin condition and typically appears on sun-exposed areas of the skin as small, rough, scaly patches. AK lesions may progress to a form of skin cancer called squamous cell carcinoma, or SCC. We believe that our lead product candidate, PEP005 Gel for AK, once developed and, if approved for commercialization by the appropriate regulatory authorities, could offer patients an effective and well-tolerated treatment alternative for AK with a short, two-to-three day application regimen that could be performed by the patient at home.

Prior to filing a new drug application, or NDA, for PEP005 Gel for AK, we will need to complete a series of clinical trials in two general anatomical areas: head, which comprises areas on the face or scalp, and non-head, which primarily comprises areas on the back of the hand, arm, shoulder, chest, legs and back. We expect this program will require four pivotal Phase 3 clinical trials comprising two Phase 3 clinical trials for non-head applications (REGION-I and REGION-Ib) and two Phase 3 clinical trials for head applications (REGION-IIa and REGION-IIb), in each case together with supportive safety and other studies. REGION-I was completed in May 2009, REGION-IIa, REGION-IIb, REGION-Ib have enrolled and results are expected by December 31, 2009. We expect to file a single NDA for applications to treat AK on both head and non-head treatment locations with the FDA by mid-calendar year 2010, assuming the successful completion of our Phase 3 clinical program.

We are also developing a product candidate containing PEP005 for the treatment of superficial basal cell carcinoma, or superficial BCC. This product candidate is a tumor-directed therapy currently in a Phase 2a clinical trial (PEP005-009) and is referred to as PEP005 Gel for BCC. BCC is the most commonly occurring cancerous skin tumor and can present itself in two forms, nodular BCC, which appears as a shiny bump or nodule that may be confused with a mole, and superficial BCC, which has a slightly raised, ulcerated or crusted surface. Our development of PEP005 Gel for BCC is at an earlier stage than that of PEP005 Gel for AK. However, we believe that this product candidate, once developed and, if approved for commercialization by the appropriate regulatory authorities, could offer patients an effective and well-tolerated treatment alternative for superficial BCC with a short one or two day application regimen.

We own patents and have filed applications that relate to the use of PEP005 and related molecules and pharmaceutical compositions of those molecules from plants in the genus *Euphorbiaceae* in the treatment of cancers, AK, pre-cancers and other diseases in the United States, Australia and New Zealand, as well as several other markets around the world, including in the European Union. In addition, we have filed patents which protect certain aspects of our product candidate formulations. We plan to develop a direct sales and marketing organization to commercialize and market PEP005 Gel for AK to the dermatology community if it receives regulatory approval. Initially, we anticipate that our sales representatives will target high prescribing dermatologists in the United States, and dermatologists and other clinicians that treat AK in Australia and New Zealand. As a result, we believe a relatively modest sales organization can effectively penetrate this market.

We were formed for the purpose of reorganizing our former parent company, Peplin Limited, into the United States. Peplin Limited, formerly known as Peplin Biotech Ltd., was formed in 1999 as an Australian company. On October 16, 2007, we acquired all the outstanding shares of Peplin Limited pursuant to a Scheme of Arrangement. We refer to this transaction as the Reorganization. Following the Reorganization, Peplin Limited became our wholly-owned subsidiary and our business and operations consist solely of the business and operations of Peplin Limited.

On September 2, 2009, we entered into an Agreement and Plan of Merger (the Merger Agreement) with LEO pursuant to which a wholly owned subsidiary of LEO will be merged with and into Peplin, with Peplin surviving the merger as a wholly owned subsidiary of LEO. The statements in this Form 10-K reflect our status as of June 30, 2009 as an independent, public company. If the merger with LEO is completed, Peplin will cease to be an independent, public company and will be a wholly subsidiary of LEO. Until the completion of the merger, we are required to comply with the terms of the Merger Agreement,

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including restrictions on the conduct of our business prior to the completion of the merger, which may affect our ability to take actions discussed in this Form 10-K.

Pre-Cancerous Skin Lesions and Skin Cancer

Repeated or prolonged exposure to ultraviolet light, the invisible but intense rays of the sun, can result in skin damage. Some of the effects, such as suntan or sunburn, are quickly visible. However, other skin changes, including liver spots and deep wrinkles, appear slowly and worsen over time. With repeated and long-term sun exposure, skin damage, particularly in fair-skinned people, may result in skin disorders including pre-cancerous skin lesions and various skin cancers.

AK is generally considered the most common pre-cancerous skin condition. AK usually appears as small, rough, scaly areas on the face, lips, ears, back of hands, forearms, scalp or neck. AK lesions may progress to a form of skin cancer called squamous cell carcinoma, or SCC.

Melanoma, SCC and BCC, are the three primary forms of skin cancer, all of which typically develop on areas of the body that are exposed to the sun. Given its propensity to rapidly spread to other organs of the body, melanoma is the most serious and difficult to treat of all skin cancers. According to the American Academy of Dermatology, melanoma accounts for approximately 4% of all new cases of skin cancer each year. SCC usually develops in the epidermis, the upper layer of the skin, and accounts for approximately 16% of all new cases of skin cancer annually. BCC develops in the basal, or lower, layer of the epidermis, and accounts for approximately 80% of all new cases of skin cancer annually. BCC can present itself in two forms, nodular BCC, which appears as a shiny bump or nodule that may be confused with a mole, and superficial BCC, which has a slightly raised, ulcerated or crusted surface. SCC and BCC, together, are often referred to as non-melanoma skin cancers.

AK and BCC are, respectively, the most commonly occurring pre-cancerous skin condition and cancerous tumor, and we expect their incidence to increase at a significant rate, given societal trends that emphasize tanning and clothing styles that expose skin, increased participation in outdoor activities and increased longevity. We are initially developing a topical gel based on our lead compound, PEP005, to treat AK and superficial BCC. However, we also intend to evaluate the utility of PEP005 in treating other skin disorders, including nodular BCC, SCC and cutaneous warts.

Existing Treatments and their Limitations

Existing treatment alternatives for AK and BCC include surgical or ablative procedures, where lesions or tumors are destroyed or cut out of the skin, topical treatments that are designed to clear the lesion or tumor through repeated application, and/or combinations of surgical or ablative procedures in conjunction with topical therapies. Currently, the primary treatment for AK is cryotherapy and the primary treatment for BCC is surgical excision. The following briefly discusses the range of existing treatment alternatives from the most invasive to least invasive.

Surgery. Surgical procedures range from curettage and desiccation, or scraping and burning of the lesion, to simple excision, to the sophisticated surgical techniques of Mohs surgery, which involves repetitive removal of cancerous tissue over several stages while maintaining as much of the surrounding healthy tissue as possible. Surgery is generally used to treat BCC, with long-term clearance rates of approximately 95% typical for Mohs surgery, dependent on the nature of the tumor and the form of surgical intervention. However, results are dependent on operator experience and technique, and physician follow-up may be needed to monitor healing. Given that other less invasive treatment alternatives are effective in treating AK, AK is not typically treated using surgical excision. Some surgical techniques, such as Mohs surgery, can be costly and time consuming and can cause pain, scarring and other unsatisfactory cosmetic outcomes, which may be particularly undesirable for treatments on the face or neck.

Cryotherapy. Cryotherapy is a quick and well-established treatment alternative in which the clinician removes individual clinically-obvious AK lesions by applying a cryogen, or extreme cold, for a sufficient period of time to destroy the lesion. The International Journal of Dermatology reported that the overall clearance rate for cryotherapy was 67.2%, ranging from 39% to 83%, depending on the freezing time. A

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December 2007 study in the British Journal of Dermatology further reports 68% overall initial clearance rate using a 20-40 second application of liquid nitrogen to individual lesions. Following this treatment, once year recurrence rates of the treated lesions was 72%. Cryotherapy has no therapeutic benefit on the surrounding area of sun damaged skin and can result in unwanted damage to surrounding healthy tissue, pain, blistering and loss of skin pigmentation, leaving permanent white spots. Like surgery, cryotherapy can lead to unsatisfactory cosmetic outcomes, which is undesirable for treatments on the face or neck. In addition, because there is no standardized treatment protocol for cryotherapy, results may not be uniform. Cryotherapy is currently the most common treatment alternative used for AK. Cryotherapy can also be used to remove small, superficial BCC tumors, but its use in BCC is not typical because surgical approaches are generally more effective.

Photodynamic therapy, or PDT. PDT involves the in-office application of a topical solution to AK lesions followed by the application of light therapy to activate the drug that has been absorbed into the skin. Typically, a patient will visit the physician s office in the morning, where the topical solution will be applied to the affected area. Once the drug has been absorbed, generally within several hours of application, the patient returns to the physician s office and the physician applies the light therapy. When the treated area of skin is exposed to a light source of an appropriate wave length and energy, the drug will attack and clear the AK lesions. The patient is advised to avoid exposure to bright light while the drug is being absorbed and, generally, for up to 40 hours after the procedure. To perform PDT procedures, the physician must make an upfront capital investment to acquire the appropriate light source and make repeated purchases of the drug. Two drugs are approved in the U.S. as photosensitizers utilized in PDT, Levulan Kerastick and Metvixia. The Levulan package insert summarizes the results of two studies in which Levulan demonstrated complete clearance of all AK lesions in 69% and 63% of patients, respectively, eight weeks after initial treatment. The Metvixia package insert includes two studies in which Metvixia achieved complete clearance of all AK lesions in 81% and 79% of patients, respectively, three months after patients received two Metvixia treatments. PDT is not indicated for the treatment of BCC in the United States.

Topical agents. As AK lesions typically emerge in an area of sun damaged skin, the goal of topical therapy has been to treat not only the obvious lesions but also the surrounding sun damaged skin to reduce the development of new or recurrent lesions. Surgery, cryotherapy and PDT are targeted at the clearance of clinically obvious AK lesions or BCC tumors. Topical agents are generally considered a field-directed therapy for AK because they are applied to an entire area of skin to treat clinically obvious lesions, subclinical lesions below the skin and not visible upon physical examination and the surrounding sun damaged skin where new lesions may develop. The following are the primary FDA-approved topical agents for treatment of AK or BCC:

Topical imiquimod: Topical imiquimod, sold as Aldara, is indicated for the treatment of AK lesions on the face or scalp, smaller superficial BCC tumors and external genital and perianal warts. Topical imiquimod activates the body s immune system, causing the migration of white blood cells to the treated area to attack and kill the damaged skin cells. According to the product s package insert, in the treatment of AK, topical imiquimod is applied by the patient twice per week for 16 weeks and demonstrated a complete clearance rate at eight weeks post treatment, or 24 weeks after commencing treatment, in 45% of patients. In addition, topical imiquimod can reveal and clear AK lesions in the skin that have not yet become clinically apparent, resulting in a further long-term benefit. During the treatment period, and for a period of time after, common side effects include erythema, or redness, dryness, scaling and crusting. Due to the intensity of these side effects, some patients are advised to take a rest period of several days during treatment. Following the treatment, an additional one to two weeks of healing is generally required. In superficial BCC applications, topical imiquimod is applied by the patient five times per week for six weeks. Topical imiquimod may be used alone to treat superficial BCC, or it may be used to de-bulk tumors prior to surgery or to treat margins after surgery.

Topical 5-FU: Topical 5-fluorouracil, or topical 5-FU, is a topical formulation of an off-patent chemotherapeutic agent. It is sold, in differing concentrations, as Efudex, Carac Fluoroplex and others, and is used primarily to treat AK lesions. Topical 5-FU acts by inhibiting the altered skin cells from making and repairing DNA, which prevents the AK cells from growing and multiplying and ultimately results in cell death. Topical 5-FU is typically applied twice-a-day by the patient for approximately two to four weeks. According to the May 2006 issue of *The Journal of Family Practice*, topical 5-FU

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demonstrated a complete clearance rate of approximately 50%. Like topical imiquimod, topical 5-FU can also treat skin lesions that have not yet become clinically apparent. While effective, the common side effects include burning, redness, pain, erosion and dryness of the skin which may continue for a period of time after therapy. The pain and unsightliness of these temporary side effects can be severe enough to affect patient tolerability and may cause the patient to prematurely terminate treatment. To reduce inflammation, a topical corticosteroid is sometimes applied. Following the treatment, an additional one to two months of healing is generally required. Topical 5-FU is not commonly used in the treatment of BCC, although it is approved for this indication.

Topical diclofenac: Diclofenac is a non-steroidal anti-inflammatory drug that has been shown to clear AK lesions. Topical diclofenac gel is currently indicated only for the treatment of AK and is marketed under the trade name Solaraze. The drug is prescribed for patient application twice-a-day for 30 to 90 days, although complete healing of AK lesions may not be evident for up to 30 days following therapy. According to the product s package insert, topical diclofenac has produced complete clearance of treated AK lesions in 18% to 47% of patients, based on the location of the lesion at 30 days post-treatment, or 60 to 120 days after initial treatment. During the extended applications of the topical agent, there may be a rash, scaling or dryness of the skin. Contact sensitization has been observed and patients are typically advised to avoid sun exposure during treatment.

Currently, cryotherapy is the most common treatment alternative used for AK. It is used as the sole approach in approximately 75% of the patients for AK lesions, and in combination with pharmacotherapy in approximately 9% of the patients. Topical drugs are used alone in approximately 16% of AK patients. Cryotherapy can also be used to remove small, superficial BCC tumors, but its use in BCC is not typical because surgical approaches are generally more effective. We believe that treatment of AK will continue to grow primarily as a function of factors such as:

growth in the incidence of AK due to the aging of the population;

better awareness of AK, sun damage and skin cancer, including the recognition of the benefits of early intervention and prevention of progression to skin cancer;

a developing understanding among clinicians that topical agents for the treatment of AK may treat both clinically obvious lesions and other lesions that may not yet be visible; and

general patient preference for less invasive and more cosmetically acceptable treatment alternatives.

We believe that existing topical therapies for AK, while successful in the marketplace, face barriers to broader adoption. The primary and most significant limitations of existing topical agents are the generally long courses of therapy, which can range from 2 weeks to 16 weeks, and the unsightly side effects of these topical agents, which may persist in the treatment area throughout the course of treatment. We believe these limitations result in general patient dissatisfaction and poor patient compliance with treatment regimens, which ultimately can result in poor treatment outcomes.

Our Solution PEP005

We are developing novel, naturally occurring compounds that we believe have the potential to treat certain skin cancers and pre-cancerous lesions, while addressing some of the limitations of existing treatment alternatives. These compounds are small molecules that we extract and purify from *Euphorbia peplus*, a rapidly growing, readily-available plant commonly referred to as petty spurge or radium weed. The sap of *E. peplus* has a long history of traditional use for a variety of conditions, and particularly topical self-treatment of various skin disorders, including skin cancer.

In our preclinical studies for PEP005 we have observed that the topical application of PEP005 has two distinct and complementary mechanisms of action. First, application of PEP005 Gel to a tumor resulted in the rapid swelling of mitochondria in the tumor cells, ultimately resulting in necrosis, or tumor cell death. Second, PEP005 activates the body s immune system, causing neutrophils, a type of white blood

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cell, to infiltrate the treated site. The white blood cells activated as a result of PEP005 treatment appear to target and destroy any residual tumor cells, which appears to limit or prevent relapse of tumors.

Our lead product candidate is a patient-applied topical gel for the treatment of AK. We are also developing a topical gel for the treatment of superficial BCC. We also intend to evaluate the utility of PEP005 in a topical formulation for treating other skin disorders, including nodular BCC, SCC and cutaneous warts.

PEP005 Gel for AK

Non-head (trunk and extremities)

In pursuit of U.S. Food and Drug Administration, or FDA, approval, we completed our first Phase 3 clinical trial, known as REGION-I, for AK as a field-directed therapy for non-head AK lesions in May 2009. REGION-I tested a 0.05% concentration of PEP005 Gel applied once a day for two consecutive days in approximately 255 patients. This resulted in a median reduction in the number of AK lesions of 66.7% (p-value<0.0001), a total clearance rate across all anatomical non-head sites, including the extremely difficult-to-treat back of hand and arm locations, equal to 27.4% (p-value<0.0001) and a partial clearance rate of 44.4% (p-value <0.0001). As anticipated, the inclusion of treatment sites for all non-head AK lesions contributed to the lower clearance rates when compared to previous trials, but the total clearance rates ranged from 16% to 89% by anatomical location with chest, back of hand and arms achieving statistical significance. Other areas did not show statistical significance due to the low number of patients that enrolled with those types of AK lesions. With this study, PEP005 Topical for AK is the first topical treatment to demonstrate statistically significant benefit over vehicle across multiple non-head anatomical locations.

Results from the trial also suggest that the drug presents a favorable safety profile. The most frequent local skin responses (LSRs) included erythema, flaking and scaling with no significant adverse effects reported. The LSRs peaked at day 8 and returned to baseline by day 29.

REGION-I was conducted under a Special Protocol Assessment, or SPA, with the FDA, which means that the FDA reviews the design, size and planned analysis of the Phase 3 clinical trial and provides comments regarding the trial s adequacy to form a basis for marketing approval with respect to effectiveness, should the trial achieve its objectives. The FDA has indicated its agreement with the design, clinical endpoints and planned statistical analyses of our proposed Phase 3 clinical trial. The FDA s agreement on the SPA is binding on it, except in limited circumstances, such as if a substantial scientific issue essential to determining the safety and effectiveness is identified after the trial is initiated.

We have initiated the second Phase 3 non-head trial for AK, known as REGION-Ib, and completed enrollment of approximately 200 patients.

Head (face and scalp)

In January 2009, we completed our PEP005-015 Phase 2b, dose ranging clinical trial of PEP005 Gel for AK over several different concentration levels as a field-directed therapy for AK lesions on head locations, which includes face and scalp. Based on the positive results from the Phase 2b AK trial (PEP005-015), a 0.015% concentration of PEP005 Gel applied once daily for three consecutive days advanced to Phase 3 development. This concentration and dosing regimen provided a median reduction in overall lesion count of 84.5%, a total clearance rate in the intent to treat population equal to 50.0% (p-value = <0.001) and a partial clearance rate of 71.9% (p-value = <0.001). The LSRs peaked at day 4 and returned to baseline by day 15 for all treatment groups. This is the dose selected for additional observation in the subsequent Phase 3 head trials, which have been initiated and are fully enrolled at 250 patients each.

As compared with other treatment alternatives, we believe that PEP005 Gel for AK could offer a combination of attractive benefits to patients seeking treatment of AK, including:

a short two-to-three day treatment regimen;

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localized, transient and well-tolerated side effects;
a mode of action distinct from other AK treatment modalities;

a convenient, patient-applied, take-home prescription medication; and

the ability to treat visible lesions and the surrounding sun damaged skin where lesions may develop in the future.

PEP005 Gel for BCC

The preliminary results from our PEP005-003 Phase 2a clinical trial of PEP005 Gel for BCC, suggest that this drug candidate presents a favorable safety profile and is well tolerated. Further, 71% of superficial BCC tumors were cleared with just two applications of 0.05% PEP005 Gel for BCC and this result was statistically significant when compared with the vehicle gel. We intend to develop PEP005 Gel for BCC as a treatment for superficial BCC tumors. We are presently conducting a further Phase 2 dose escalation clinical trial, which we call PEP005-009, in which we are increasing the concentration of PEP005 Gel for BCC to establish the maximum tolerated doses, or MTDs, when administered as a single application and when administered as two applications one week apart. We plan to evaluate the histological tumor clearance rate at the MTDs. We must successfully complete these and other trials before we can seek regulatory approval to commercialize this product candidate. We do not expect to commence our Phase 3 clinical program for PEP005 Gel for BCC until calendar year 2010.

The vast majority of BCC tumors are treated by surgical methods. However, we believe that the associated pain and morbidity, together with the potential for long-term surgical scars that accompany surgery represent an important shortcoming of this treatment approach. Further, we believe that physicians and their patients would embrace an effective and well-tolerated topical alternative to surgery. We believe PEP005 Gel for BCC has the potential to be a prominent treatment option for smaller and well demarcated superficial BCC tumors.

Clinical Development Program

PEP005 Gel for AK

We are developing PEP005 Gel for AK as a prescription, patient-applied, take-home, topical medication available in single-use tubes. We expect that commercial packages will consist of two tubes for non-head treatment areas and three tubes for head treatment areas and be sufficient for a course of treatment of a 25 square centimeter area, which, for example, approximates half the sun damaged area to be treated on the typical forehead or cheek.

Clinical Overview. We are developing PEP005 Gel for AK under an Investigational New Drug, or IND, application filed with the FDA in June 2004. To date, we have completed twelve clinical trials in our AK program with greater than 950 subjects treated with active drug. Our early trials focused on evaluating the safety and preliminary efficacy of PEP005 Gel for AK as a lesion-directed therapy. Lesion-directed therapy, in this case, refers to the application of PEP005 Gel for AK to the AK lesion and immediate peri-lesional skin area only. As our clinical trials for AK progressed, we have transitioned from the evaluation of PEP005 Gel for AK as a lesion-directed therapy to its evaluation as a field-directed therapy. Field-directed therapy refers to the application of PEP005 Gel for AK to a broader area of sun damaged skin that includes the AK lesions. We plan to conduct supportive safety and other studies in parallel with our future clinical trials in support of our NDA filing.

In each of our completed clinical trials, PEP005 Gel for AK has suggested a favorable safety profile. Localized redness, flaking or scaling and crusting were the most common local skin responses reported in our trials. All of these reactions were transient and generally cleared within two to four weeks following treatment. Significantly, no scarring, clinically relevant change in pigmentation or other longer term complications have been observed. Our trials indicate that PEP005 Gel for AK may clear AK lesions with a single application applied each day for a period of two or three days.

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Evaluation Metrics. As part of our clinical trial program, we evaluate the safety of our drug candidate, each patient s skin response at the treatment site. We evaluate safety based on the occurrence of adverse events and serious adverse events, or adverse events that are life threatening in nature. We evaluate the patient s skin response at the treatment site based on a subjective evaluation made by the investigator using a numerical scale designed to measure the intensity of the skin response. Some response at the treatment site is desirable, because it indicates the site is responding to treatment. Typical skin responses include redness, flaking or scaling, crusting, swelling, blistering and ulceration.

We evaluated clearance rates in our REGION-I (Phase 3, non-head), PEP005-006 (Phase 2, non-facial), PEP005-015 (Phase 2b, head), PEP005-007 (Phase 2a, head) clinical trials using three efficacy metrics:

Partial AK lesion clearance rate. This rate is defined as the proportion of patients in the trial who, on the 57th day post-treatment, manifested 75% or greater reduction in the number of AK lesions identified at baseline in the treatment area.

Complete AK lesion clearance rate. This rate is defined as the proportion of patients in the trial who, on the 57th day post-treatment visit, manifested no clinically visible AK lesions in the treatment area whether they existed at the baseline measurement or manifested during the trial period.

Median percent reduction in lesion court. This rate is defined as the median percent reduction in the number of lesions identified in the treatment are at the 57th day post-treatment, compared to the number of lesions identified of baseline.

REGION-I (PEP005-014) Clinical Trial. REGION-I was a 255-patient, multi-center, randomized trial of a 0.05% concentration applied once a day for two consecutive days for Peplin s patented product, PEP005 Gel in patients with AK lesions on non-head sites. The mean age of patients was 67.1 years (range 36 88 years), 62.4% of patients were male and 37.6% female. Patients were randomized across the six anatomical locations as follows: 166 (65.1%) arm, 54 (21.2%) back of hand, 17 (6.7%) chest, 2 (0.8%) shoulder, 5 (2.0%) back and 11 (4.3%) leg.

Safety and Tolerability: Results from the trial also suggest that the drug presents a favorable safety profile with the most frequent LSRs included erythema, flaking and scaling with no significant adverse effects reported. The LSRs peaked at day 8, resolved by day 29.

Efficacy: Efficacy was evaluated 57 days post-treatment using the intent to treat patient population, which consisted of all patients randomized into the study. The statistical significance of the difference in the clearance rates of active treatment groups compared to vehicle treatment groups is presented in terms of p-value in the chart below. A 0.05% concentration of PEP005 Gel applied once daily for two consecutive days resulted in a total clearance rate in the intent to treat population equal to 27.4% (p-value<0.0001), a partial clearance rate of 44.4% (p-value<0.0001) and a median reduction in overall lesion count of 66.7% (p-value<0.0001).

		Overall		Chest		Arm		Back of Hand	
Efficacy measure	**Vehicle**	**%**	**p-value**	**%**	**p-value**	**%**	**p-value**	**%**	**p-value**
Complete AK lesion clearance rate	5%	27%	<0.0001	89%	0.0034	25%	0.0002	16%	0.0400
Partial clearance rate		44%		89%		48%		24%	
Median % reduction		67%		100%		73%		50%	

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Moving Forward: We have initiated the second Phase 3 non-head trial for AK, known as REGION-Ib, and completed enrollment of approximately 200 patients.

PEP005-015 Clinical Trial Our PEP005-015 clinical trial was a multi-center, randomized, double-blind vehicle-controlled, dose-ranging clinical trial designed to evaluate the safety, tolerability and efficacy of each of 0.005%, 0.010%, or 0.015% PEP005 Gel for AK as field-directed therapy for AK lesions on head locations. The trial treated 265 patients, 237 male and 28 female, with a mean age of 67 years. Patients participating in this trial were randomized into one of eight treatment arms, with each arm consisting of treatment with either vehicle gel or one of 0.005%, 0.010% or 0.015% PEP005 Gel for AK and such treatment occurring over two or three consecutive days. Patients in each treatment arm applied the treatment at home to a 25 square centimeter area containing four to eight AK lesions.

Safety and Tolerability. At all concentrations of active drug, for both the two day and three day treatments, the PEP005 Gel demonstrated a favorable safety profile and was well tolerated. The most common side effects were primarily transient, short-term, LSRs at the treatment site which generally peaked at day 4 and returned to baseline by day 15. There were no drug related serious adverse events reported in the trial.

Efficacy. Complete clearance rates ranged from 15.6% to 42.3% across the six active treatment groups that achieved statistical significance. The highest dose group with a 0.015% concentration of PEP005 Gel applied once daily for three consecutive days was selected for further study in Phase 3 trials. The selected dose resulted in a total clearance rate in the intent to treat population equal to 50.0% (p-value=<0.001) and a partial clearance rate of 71.9% (p-value= <0.001). The selected dose provided a median reduction in overall lesion count of 84.5%

		Overall	
Efficacy Measure	**Vehicle**	**%**	**p-value**
Complete AK lesion clearance rate	9.1%	50.0%	<0.001
Partial clearance rate		71.9%	<0.001
Median % reduction		84.5%	

Moving Forward: We initiated our two Phase 3 head trials for AK, known as REGION-IIa and REGION-IIb, and completed enrollment of approximately 250 patients in each.

AK Clinical Development Plan.

Prior to filing a NDA, for PEP005 Gel for AK, we will complete a series of clinical trials in two general anatomical areas, head, which comprises areas on the face or scalp, and non-head, which primarily comprises areas on the back of the hand, arm, shoulder, chest, leg and back. Our program includes four pivotal Phase 3 clinical trials comprising two Phase 3 clinical trials for non-head applications (REGION-I and REGION-Ib) and two Phase 3 clinical trials for head applications (REGION-IIa and REGION-IIb), in each case together with supportive safety and other studies. REGION-I was completed in May 2009 with details provided above.

REGION-IIa and REGION-IIb (Phase 3, head). The REGION-II trials are both multi-center, randomized, double-blind, vehicle-controlled studies. Each trial enrolled approximately 250 patients. Patients self apply the study medication (0.015%) or vehicle gel for three consecutive days to a 25 square centimeter treatment area containing four to eight AK lesions on the face or scalp. The studies are designed to replicate the positive results demonstrated in earlier trials, specifically the results of the Phase 2b trial (PEP005-015) announced earlier in calendar year 2009. Consistent with previous trials, the primary efficacy endpoint is the complete clearance rate of AK lesions and the secondary efficacy endpoint is the partial clearance rate of AK lesions within the treatment area. Peplin is also measuring the overall median percent reduction in AK lesion count.

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REGION-Ib (Phase 3, non-head). This is the second pivotal Phase 3 trial for non-head locations designed to replicate the recently completed REGION-I trial and confirm the results of PEP005 Gel. REGION-Ib is a randomized, multi-center, double-blind, vehicle-controlled clinical trial. Peplin enrolled approximately 200 patients who will self-apply the study medication (0.05%) or vehicle gel for two consecutive days to a 25 square centimeter treatment area containing four to eight AK lesions. Consistent with prior trials, the primary efficacy endpoint will be the complete clearance rate of AK lesions and the secondary efficacy endpoint will be the partial clearance rate of AK lesions within the treatment area. Peplin will also measure the overall median percent reduction of AK lesions.

PEP005 Gel for BCC

We are developing PEP005 Gel for BCC as a tumor-directed treatment for superficial BCC that is designed for application using a delivery device to accurately administer a quantity of drug calibrated to tumor size and volume. We are currently evaluating various treatment regimens in which PEP005 Gel for BCC is applied to tumors at either one or two office visits, with the two office visits occurring a week apart, at drug quantities that vary depending on the size of the tumor.

Clinical Overview. We are developing PEP005 Gel for BCC under a separate IND filed with the FDA in June 2004. To date, we have completed two Phase 2a clinical trials in the BCC program with a total of 118 patients treated, and have a third Phase 2a trial of approximately 50 patients that is ongoing. We also plan to commence and complete a Phase 2b trial before we begin planning our Phase 3 pivotal clinical trials. We relied on data from our AK Phase I trials to enable initiation of the program for superficial BCC at a more advanced stage. Our phase 2b trial has focused on tumor-directed therapy for non-facial superficial BCC tumors. Unlike our AK clinical development program, we do not intend to evaluate PEP005 Gel for BCC as a field-directed therapy.

Across our completed BCC trials, PEP005 Gel for BCC has suggested a favorable safety profile, with the most common LSR being redness. Moreover, no drug-related serious adverse events have been reported in these trials, and no patients have discontinued the trial due to adverse events.

Preliminary efficacy evaluation has shown that tumor clearance may be achieved with one to two doses of PEP005 Gel for BCC.

PEP005-003 Clinical Trial. PEP005-003 was a Phase 2a, multi-center, double-blind, randomized, vehicle-controlled, parallel group trial designed to assess the safety of PEP005 Gel for BCC at three concentrations. The trial s secondary objectives were to determine an appropriate treatment regimen and to provide preliminary efficacy evaluation of PEP005 Gel for BCC.

We enrolled 60 patients in the trial and randomized them to one of two treatment arms: one that received treatment on days 1 and 2, and one that received treatment on days 1 and 8. Each treatment arm consisted of four treatment groups with each group receiving one of the following concentrations: 0.0025%, 0.01% or 0.05% PEP005 Gel or vehicle gel. Patients were required to have a biopsy-confirmed superficial BCC located on the arm, shoulder, chest, face, neck, leg or back. The median tumor diameter was 9 millimeters, with a range of 4 to 15 millimeters. PEP005 Gel for BCC in the amount of 70 or 100 microliters, depending on tumor size, was applied to the superficial BCC once daily on each of the two treatment days. All applications of PEP005 Gel for BCC were performed in a physician s office by a clinician. Patients were then monitored for 12 weeks. All but two patients completed their two day courses of therapy.

The preliminary results of the trial demonstrated that PEP005 Gel for BCC was well-tolerated with a favorable safety profile. The majority of LSRs were mild to moderate. The most frequently reported LSR was redness. LSRs typically resolved within four weeks and all LSRs were resolved by the end of the trial. There were no drug-related serious adverse events reported.

The primary evaluation of efficacy was the histological clearance rate determined from examination of excised treatment sites at the 12-week evaluation visit. The trial suggested a dose related response to the drug. The most effective concentration of PEP005 Gel for BCC was the highest concentration. In the group that

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received treatment on days one and two, 71% of the superficial BCCs from a total number of seven were completely cleared versus 0% of the six in the vehicle group. This difference was statistically significant with a p-value of 0.02.

PEP005-009 Clinical Trial. Our PEP005-009 clinical trial is an ongoing Phase 2 dose escalation trial designed to determine the MTD of PEP005 Gel for BCC. A total of 60 patients have been enrolled in the dose escalation phase of this trial. PEP005 Gel for BCC is being administered to superficial BCC tumors on the trunk as either a single application or two applications occurring one week apart. Secondary objectives of this trial include an evaluation of tumor clearance rates. All applications of PEP005 Gel for BCC are being performed in a physician s office by a clinician.

BCC Clinical Development Plan. We expect the clinical safety and preliminary efficacy data from our PEP005-009 and future Phase 2 trials in superficial BCC patients to allow us to define an appropriate concentration and treatment regimen. Prior to initiation of the Phase 3 program, we will meet with the FDA to review preclinical, manufacturing and clinical data and to discuss the design of Phase 3 trials.

Third-Party Independent Contract Research Organizations

We do not currently conduct clinical trials on our own, and instead rely on independent clinical research organizations, or CROs, to provide us with clinical trial monitoring and administration services. Furthermore, in the future we may need to rely on other CROs to provide us with support and administration services. Pursuant to Clinical Master Services Agreements with CROs, we submit project protocols on an as needed basis to the CRO which then administers the trial pursuant to the terms of the protocol and our directions. The Clinical Master Services Agreements, or any project protocol, is terminable by either party on 30 to 60 days notice, provided that the CRO cannot terminate if a project remains incomplete. We also depend on independent clinical and non-clinical investigators to provide services in connection with our preclinical pharmacology and toxicology research and development and our clinical trials. Our preclinical pharmacology and toxicology research and development and our clinical trials are conducted by a number of third parties at a number of different sites in different jurisdictions, including the United States, the United Kingdom, Australia and New Zealand, and these third parties play a significant role in the conduct of these studies and the subsequent collection and analysis of data. We own no laboratories or other research space and, therefore, must rely on third parties for these services. To date, we have been able to manage the use of these third parties in order to effectively carry out our preclinical pharmacology and toxicology research and development and our clinical trials.

Intellectual Property

We own patents and have filed applications that relate to the use of PEP005 and related molecules and pharmaceutical compositions of those molecules from plants in the genus *Euphorbiaceae* in the treatment of cancers, AK, pre-cancers and other diseases in the United States, Australia, New Zealand, as well as several other markets around the world, including in the European Union. In addition, we have filed patents which protect certain aspects of our product candidate formulations. In total, we own exclusive rights to three patents and seven patent applications in the United States, and 34 patents and 9 patent applications (including one pending Patent Cooperation Treaty application) outside the United States, relating to uses and formulations of PEP005. We also have three pending Patent Cooperation Treaty applications relating to our products. Our issued U.S. and non-U.S. patents expire between August 2018 and August 2026, subject to any patent term extension which might be available under the Hatch-Waxman legislation or similar laws in Europe and other foreign jurisdictions. Of these issued patents and patent applications, four and seven, respectively, relate to the treatment of skin cancers, including SCC, BCC and AK. We also have patents and patent applications related to the treatment of other conditions, including solid cancers, tumors, colon cancer, bladder cancer, prostate cancer, cervical cancer, breast cancer and warts. All of our patent and patent applications relate to technology that we have developed in-house or have exclusive rights to. In addition, we rely on trade secrets and contractual arrangements to protect certain aspects of our proprietary information and products.

We believe that we were the first to document, in a controlled setting, the clinical utility of *E. peplus* in the treatment of certain forms of skin cancer and pre-cancerous lesions and further to isolate,

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characterize and validate the single molecular entity responsible for the anti-skin cancer effects of the plant sap. We believe our patents protect our proprietary rights to the use of PEP005 and related molecules, generally, angeloyl substituted ingenanes, whether obtained or obtainable from *E. peplus*, in the treatment of skin cancer, precancerous lesions, cancer in general and a variety of other conditions and diseases.

We own patents and patent applications related to the following:

- the use of PEP005 and related compounds in the treatment of cancer, skin cancer, pre-cancerous lesions, AK and a number of other dermatologic, oncologic and other diseases;
- formulations that stabilize and optimize the delivery of PEP005 and related compounds; and
- immune stimulating properties, wound healing, combinations with other anti-cancer agents and biomarkers of sensitivity.

Effective October 16, 2008, we acquired all of the outstanding shares of Neosil, Inc., or Neosil, a privately held, dermatology-focused company. The purchase price was 819,378 shares of our common stock. Following the close of the transaction, Neosil became our wholly-owned subsidiary. In addition to its net cash of approximately $6.7 million, Neosil also owns an intellectual property portfolio comprising of two early clinical stage development programs: the first, a hair growth stimulation technology with potential application in the treatment of hair loss and the second, a broad spectrum anti-microbial technology with potential application in the treatment of acne. Neosil owns rights to 16 patents and 3 patent applications covering its two development programs in the United States. In addition, Neosil owns rights to 35 foreign patents and 25 pending foreign patent applications. Neosil s issued patents expire between 2013 and 2020. We are not presently conducting further development of the Neosil intellectual property.

Manufacturing

The production process for PEP005 involves cultivation, extraction and purification. PEP005 is then formulated in a gel and filled in a tube. *E. peplus* grows on a number of continents, including Australia, North America and Europe. We currently contract with five growers which are localized to our manufacturing facility in Queensland, Australia to cultivate our raw supply of *E. peplus*. We expect that the yearly supply from these growers will be adequate for the next several years. In Australia, *E. peplus* can be grown during approximately nine months of the year and it typically takes 16 weeks from the time of planting to the harvest of the mature plant. We also store dried *E. peplus* to manage potential supply variations. We are continually seeking alternative suppliers and expect to look for alternatives, including suppliers outside of Queensland, Australia, to meet our potential future commercial needs.

We operate our leased manufacturing facility for the drying, milling, extracting and purifying of pharmaceutical grade PEP005. Following receipt of the raw *E. peplus*, we use a proprietary extraction and purification technology to produce isolated crystalline PEP005 under current Good Manufacturing Practices, or cGMP, and to specified purity. Synthetic production technologies have been evaluated, but were rejected as too complex and expensive. Our manufacturing facility is located in Southport, Queensland, Australia. Horticultural and other activities are undertaken by various outside contractors based in southeast Queensland, Australia. The drug product used in clinical trials is a non-sterile gel in which crystalline PEP005 is completely dissolved. Gel formulations prepared for topical clinical trials and cGMP stability trials consist of the drug dissolved in benzyl alcohol then added to isopropyl alcohol and mixed with citrate buffer and hydroxyethyl cellulose. All process parts are manufactured separately and then combined under controlled mixing conditions to form a homogeneous bulk product. Currently, formulation, filling and packaging of our AK product candidates is undertaken by DPT Laboratories, Ltd., or DPT, a contract manufacturing organization in San Antonio, Texas. Pursuant to our development and clinical supply agreement with DPT, DPT is responsible for supplying us with PEP005 Gel for AK in quantities sufficient for our Phase 2b and Phase 3 clinical trials. Clinical batches are formulated, filled and packaged under cGMP conditions at DPT s facilities in San Antonio, Texas. The clinical supplies are then shipped to locations designated by us or our clinical research organization for use in trials. Our development and clinical supply agreement with DPT has a four-year term, ending October 2011. We may

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terminate the agreement for any reason upon thirty days written notice to DPT. DPT may terminate the agreement upon thirty days written notice to us upon our uncured breach or our insolvency.

Sales and Marketing

We plan to develop a sales and marketing organization to commercialize PEP005 Gel for AK and to promote it to the dermatology community when it receives regulatory approval.

Competition

There are various approaches to the treatment of AK, including cryotherapy with liquid nitrogen, topical therapy and photodynamic therapy, or PDT. The currently marketed topical therapies in the United States are: Carac (Dermik Laboratories), Efudex (Valeant Pharmaceuticals), Solaraze (PharmaDerm), Aldara (Graceway Pharmaceuticals) and Fluoroplex (Allergan), as well as generic fluorouracil (Oceanside Pharmaceuticals, Spear Pharmaceuticals and Taro Pharmaceuticals). Several companies, including Meda, iNova Pharmaceuticals, Valeant Pharmaceuticals and Shire, market topical therapies for the treatment of AK outside of the United States. Other therapies are known to be under development by AGI Dermatics, Graceway, Meda, TopoTarget, Medigene, Heidelberg Pharma, Grannus BioSciences, Cinuvel, Quest PharmaTech, Provectus Pharmaceuticals and KGK Synergize.

There are two photosensitizing agents currently used with photodynamic therapy for the treatment of AK, Levulan (DUSA Pharmaceuticals) and Metvixia (PhotoCure). PhotoCure recently received approval to market Metvixia in the United States and entered into a marketing agreement with Galderma for countries outside of the Nordic region for certain dermatology indications. Biofrontera and Photonamic/Medac are also developing a photosensitizing agent for use in PDT.

The pharmaceutical industry is highly competitive, and many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing, and obtaining regulatory approvals to market products for healthcare. Our competitors may succeed in developing products that are safer or more effective than ours and in obtaining regulatory marketing approval of future products before we do. Our competitiveness may also be affected by our ability to manufacture and market our products, and by the level of reimbursement for the cost of our drug and treatment by third-party payers, such as insurance companies, health maintenance organizations and government agencies.

Third-Party Reimbursement

In both domestic and foreign markets, our ability to commercialize successfully and attract strategic partners for our product candidates depends in significant part on the availability of adequate coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare, Medicaid and Veterans Affairs programs, as well as private health insurers, including managed care organizations, and other third-party payers. Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs as well as examining their cost effectiveness. Any third-party payer determination that our product candidates are not cost-effective or any significant cost containment measures could have a material adverse effect on our ability to operate profitably.

In addition, political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes, and we are unable to predict what legislation, regulations or policies, if any, relating to our industry and products may be enacted in the future. For instance, on December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act, or MMA, which, among other things, changed significantly the way that Medicare covers and reimburses certain pharmaceutical products. The new law created a new Part D prescription drug benefit which, beginning January 1, 2006, provided Medicare beneficiaries with subsidized prescription drug coverage from private sector providers, or Part D plan sponsors. Under the MMA, plan sponsors can limit the

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number of prescription drugs that will be covered in each therapeutic category and class on their formularies.

Provided we obtain FDA clearance or approval for our products and begin to market them, we anticipate that Medicare will cover PEP005 Gel for AK and PEP005 Gel for BCC under the Part D prescription drug benefit as a new class of patient self-administered therapies. We cannot be certain, however, that any of our product candidates will successfully be placed on Part D plan formularies, nor can we predict the negotiated price for our drug candidates under Part D, which will be determined by market factors.

Government Regulation

United States

Prescription drug products are subject to extensive pre-and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion of such products under the Federal Food Drug and Cosmetic Act, or FFDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. All applications for FDA approval must contain, among other things, information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, and quality control.

NDA. Approval of a NDA by the FDA is required before a drug may be marketed in the United States. This process generally involves:

completion of preclinical laboratory and animal testing in compliance with the FDA s good laboratory practice, or GLP, regulations;

submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA s current cGMP regulations; and

submission to and approval by the FDA of an NDA.

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the trial until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice regulations, including regulations for informed consent.

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For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following three phases, which may overlap:

Phase 1: Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.

Phase 2: Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the preliminary efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, a sponsor may decide to run what is referred to as a Phase 2b evaluation, which is a second, confirmatory Phase 2 trial that could, if positive and accepted by the FDA, serve as a pivotal trial in the approval of a product candidate.

Phase 3: These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor s agreement to conduct additional clinical trials to further assess the drug s safety and effectiveness after NDA approval. Such post approval trials are typically referred to as Phase IV studies.

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive manufacturing information. Once the submission has been accepted for filing, by law the FDA has 180 days to review the application and respond to the applicant. In 1992, under the Prescription Drug User Fee Act, or PDUFA, the FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times Standard Review and Priority Review. Standard Review is applied to a drug that offers at most, only minor improvement over existing marketed therapies. The 2002 amendments to PDUFA set a goal that a Standard Review of an NDA be accomplished within a ten-month timeframe. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes the FDA to review an NDA is reduced such that the goal for completing a Priority Review initial review cycle is six months. It is likely that our product candidates will be on a ten-month initial review cycle. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these postmarketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or

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labeling, expedited reporting of certain adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA s drug approval process and the agency s efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements.

Special Protocol Assessment. We utilized the procedure called Special Protocol Assessment for PEP005 Gel for AK in connection with our REGION-I, Phase 3 clinical trial for non-head applications. Under this procedure, a sponsor may seek the FDA s agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. The FDA has indicated its agreement with the design, clinical endpoints and planned statistical analysis of our proposed Phase 3 clinical trial. The FDA s agreement may not be changed after the trial begins, except in limited circumstances. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness.

Manufacturing cGMP Requirements. We and our contract manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA s cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. 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.

Other Regulatory Requirements. With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for 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 penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

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Australia

The commercialization of our product candidates will be subject to regulation by governmental entities in Australia and other countries in which we intend to market our products. Approval for inclusion in the Australian Register of Therapeutic Goods is required before a pharmaceutical drug product may be marketed in Australia. This process generally involves:

completion of preclinical laboratory and animal testing;

submission to the Therapeutic Goods Administration, or TGA, of a clinical trial notification, or CTN, or a clinical trial exemption, or CTX, application for human trials;

in the case of a CTN, submission of an investigator s brochure, clinical protocols, related patient information and supporting documentation to the Human Research Ethics Committee, or HREC, of each institution at which the trial is to be conducted;

in the case of a CTX, information relating to the overseas status of the medicine, proposed usage guidelines, a pharmaceutical data sheet and a summary of preclinical and clinical data to the HREC of each institution at which the trial is to be conducted;

adequate and well-controlled clinical trials to demonstrate the safety and efficacy of the product;

compilation of evidence which demonstrates that the manufacture of the product complies with the principles of cGMP;

and submission of the manufacturing and clinical data to, and approval by, the Drug Safety and Evaluation Branch of the TGA.

The testing and approval processes for a drug require substantial time, effort and financial resources. Furthermore, post-market surveillance must be carried out, and any adverse reactions to the drug must be reported to the TGA. We cannot make any assurances that any approval will be granted on a timely basis, if at all.

Preclinical studies include laboratory evaluation of the product as well as animal studies to assess the potential safety and efficacy of the product. The results of the preclinical studies are submitted to each investigator s HREC and in some instances, to the TGA. Approval by each HREC and by the TGA is generally necessary before clinical trials can commence. An HREC is an independent review committee at each institution at which a study is conducted and is set up under guidelines of the Australian National Health and Medical Research Council. The role of an HREC is to ensure the protection of rights, safety, and wellbeing of human subjects involved in a clinical trial by, among other things, reviewing, approving, and providing continuing review of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. We cannot make any assurances that submission to the applicable HRECs and the TGA will result in authorization to commence clinical trials. Clinical trials involve administering the investigational product to healthy volunteers or patients under the supervision of a qualified principal investigator. The TGA has developed guidelines for a CTN and a CTX, the two routes for conducting clinical trials in Australia. Under the CTN scheme, all material relating to the proposed trial is submitted directly to the HREC. The TGA is formally notified by submission of a CTN application but does not review the safety of the drug or any aspect of the proposed trial. The HREC is responsible for approving the protocol for the clinical trial. The approving authority of each institution gives the final approval for the conduct of the clinical trial, having due regard to advice from the HREC. Following approval, responsibility for all aspects of the trial conducted under a CTN application remains with the HREC of each investigator s institution and with us. A CTX application requires submission of preclinical, clinical and manufacturing data to both the TGA and the HREC of the institution at which the trials are to be conducted. A CTX trial cannot be commenced until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from the HREC of the institution at which the trials are to be conducted. The role of the TGA is primarily to assess safety

issues. The role of the HREC is to consider the scientific and ethical issues of the proposed clinical trial protocols.

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For purposes of a TGA submission and approval, clinical trials are typically conducted in three sequential phases that may overlap and are similar to the trials typically conducted for purposes of an NDA submission to the FDA:

Phase 1: clinical trials that involve the initial introduction of the drug into human subjects and the exploration of its safety (adverse effects), dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

Phase 2: clinical trials that evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks. Phase 2 trials usually involve studies in a limited patient population.

Phase 3: clinical trials that generally further evaluate clinical efficacy and further test for safety within an expanded patient population sufficient to provide statistically significant data.

In order to obtain Australian marketing approval for a drug, the results of the preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the Drug Safety and Evaluation Branch of the TGA with a request for approval to market the product by inclusion of the drug in the Australian Register of Therapeutic Goods. For major applications, the Drug Safety and Evaluation Branch of the TGA may refer the application to the Australian Drug Evaluation Committee for advice. Before approval, the TGA will require acceptable evidence of the standard of manufacture of the drug and compliance with cGMP. The Drug Safety and Evaluation Branch of the TGA may delay approval if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed.

We are currently licensed by the TGA under the Australian Therapeutic Goods Act to carry out the manufacture of the active pharmaceutical ingredient in PEP005.

Employees

As of June 30, 2009, we had 40 employees.

Item 1A. ***Risk Factors***

Risks Related to Our Business and Industry

We have incurred net losses since inception and anticipate that we will continue to incur losses for the foreseeable future.

We are a development stage pharmaceutical company with no products approved for commercial sale, and we may never be able to develop a marketable product. To date, we have funded our operations principally through the issuance of securities in Australia, the entrance by Peplin Limited, our wholly-owned subsidiary, into a $15 million loan agreement with General Electric Capital Corporation, as agent for the lenders party thereto, on December 28, 2007 (the GE Loan Agreement), and other domestic and international capital raising activities. We are not profitable and have incurred net losses in each year since inception in 1999. We have only generated a limited amount of grant income and license fee revenue from our collaborative relationships, and we have never generated any revenue from product sales. We do not anticipate that we will generate revenue from the sale of products in the foreseeable future. We have not yet submitted any products for approval by regulatory authorities and we do not currently have rights to any products that have been approved for marketing. We continue to incur research and development and general and administrative expenses related to our operations. Our net loss for the years ended June 30, 2008 and 2009 was $25,956,248 and $43,867,658, respectively. As of June 30, 2009, we had an accumulated deficit of $115,930,501. Net cash used in operating activities was $28,356,048 during the year ended June 30, 2009. We expect to continue to incur net losses for the foreseeable future. We expect these losses to increase as we continue our research activities and conduct development of, and seek regulatory

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approvals for, our product candidates, and as we prepare for and begin to commercialize any approved products. We also expect to incur increased general and administrative expenses in support of our increased operations. Over the longer term, the costs referred to above will fluctuate and will primarily depend on the number and type of clinical trials being undertaken by us at any one time. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our product candidates do not achieve market acceptance and are not successfully commercialized, we may never become profitable.

We are dependent on the success of our lead product candidate PEP005 Gel for AK, which is in development, and we cannot give any assurance that it will be successfully commercialized.

Our business is dependent on the success of our lead product candidate, PEP005 Gel for AK, a topical gel for the treatment of AK, which has not yet been successfully commercialized. We are not permitted to market PEP005 Gel for AK in the United States until we have submitted and received approval of a NDA from the U.S. Food and Drug Administration, or FDA, or in any other country, including Australia and New Zealand, until we receive the requisite approval from such countries. Before we can seek regulatory approval, we must successfully complete our clinical trials underway and future trials that we have not yet begun. We do not believe we will be able to submit a single NDA for PEP005 Gel for AK until mid-calendar year 2010.

Given the early stage of development of PEP005 Gel for AK, which contains an untested new chemical entity with a novel mode of action and is the first of a new class of investigational agents, we believe that it may be more challenging to develop and commercialize than products which incorporate either molecules of already existing classes with a well understood mode of action or which are not new chemical entities. If these challenges prove insurmountable or if any of these risks materialize, they may cause a material adverse effect on our business, prospects, financial condition and results of operations.

If we are not able to successfully complete a Phase 3 clinical trial program, we will not be able to commercialize PEP005 Gel for AK. Furthermore, even if we complete these clinical trials, the FDA may require us to perform further studies before we can commercialize PEP005 Gel for AK.

The safety and efficacy of PEP005 Gel for AK may not be demonstrated in our current or future clinical trials. The FDA generally requires successful completion of at least two adequate and well-controlled Phase 3 clinical trials prior to the submission of an NDA. While we believe that our four Phase 3 trials, two for head and two for non-head applications, will serve as our two required adequate and well-controlled studies for each application, the FDA upon reviewing the results of the trials may disagree and require us to conduct one or more additional Phase 3 clinical trials to support our NDA approval for either of these applications. In this event, we may not have adequate financial or other resources to pursue this product candidate for either or both indications through the clinical trial process or through commercialization.

Our PEP005 product candidate for the treatment of superficial BCC is at a much earlier stage than our AK treatment, and we cannot assure you that this product candidate will advance to Phase 3 clinical trials in a timely manner, if ever.

We are currently developing a product for the treatment of superficial basal cell carcinoma, or superficial BCC, which we call PEP005 Gel for BCC. We are currently evaluating this product candidate when used as a tumor-directed therapy in a Phase 2 clinical trial designed to assess safety and dosage tolerance. We must complete this trial, and potentially others, before we can commence our Phase 3 clinical trials for this application. We expect that we will have to conduct two successful Phase 3 clinical trials for BCC before we can submit an NDA for this indication.

Results of clinical trials of PEP005 Gel for AK do not necessarily predict the results of clinical trials involving other indications. Clinical trials for PEP005 Gel for BCC may fail to show the desired safety and efficacy, despite favorable results from earlier clinical trials involving AK. Moreover, because superficial BCC is a cancerous condition, the FDA and regulatory agencies in other countries are likely to require our future BCC trials to be longer and more complex than trials for AK, which is a pre-cancerous condition. We expect these trials would be more time consuming and costly. Any failure or significant delay in

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completing clinical trials for PEP005 Gel for BCC would delay our ability to submit an NDA for its approval and ultimately market this product.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining regulatory approvals for our product candidates for a target indication, we must demonstrate with substantial evidence gathered in well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

The results from the preclinical and clinical trials that we have completed for our product candidates may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any product candidate. For example, all of our clinical trials have evaluated treatment areas that are equal to or less than 25 square centimeters. In future clinical trials, we expect to evaluate and document the safety profile of PEP005 Gel for AK when applied to larger treatment areas, either individually or in the aggregate. We cannot assure you that we will be able to safely dose larger treatment areas.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- we may be unable to demonstrate that a product candidate presents an advantage over existing therapies, or over its vehicle in any indications for which the FDA requires the results of a product to be measured against its vehicle, which is the portion of the product that does not have an active pharmaceutical ingredient;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If our product candidates are not shown to be safe and effective in clinical trials, our clinical development programs could be delayed or terminated. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of post-approval clinical trials, which may be costly. In addition, the FDA may not approve the labeling

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claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Any failure to obtain regulatory approval of our product candidates would limit our ability to ever generate revenues.

We may not be successful in obtaining Australian and other foreign country regulatory approvals for PEP005 Gel for AK.

The commercialization of our product candidates will be subject to regulation by governmental entities in Australia and other countries in which we intend to market our products. In particular, our products will be subject to regulation by the TGA, under the Australian Therapeutic Goods Act, and by comparable agencies and laws in foreign countries. Approval for inclusion in the Australian Register of Therapeutic Goods is required before a pharmaceutical drug product may be marketed in Australia. This process generally involves:

completion of preclinical laboratory and animal testing;

submission to the TGA of a clinical trial notification, or a clinical trial exemption application for human trials;

in the case of a clinical trial notification, submission of an investigator s brochure, clinical protocols, related patient information and supporting documentation to the HREC of each institution at which the trial is to be conducted;

in the case of a clinical trial exemption, information relating to the overseas status of the medicine, proposed usage guidelines, a pharmaceutical data sheet and a summary of preclinical and clinical data to the HREC of each institution at which the trial is to be conducted;

adequate and well-controlled clinical trials to demonstrate the safety and efficacy of the product;

compilation of evidence which demonstrates that the manufacture of the product complies with the principles of cGMP; and

submission of the manufacturing and clinical data to, and approval by, the Drug Safety and Evaluation Branch of the TGA.

The testing and approval processes for a drug require substantial time, effort and financial resources. Furthermore, post-market surveillance must be carried out, and any adverse reactions to the drug must be reported to the TGA. We cannot make any assurances that any approval will be granted on a timely basis, if at all. Product development and approval within this regulatory framework is uncertain, could take a number of years and require the expenditure of substantial resources. Any failure to obtain regulatory approval or any delay in obtaining such approvals could have a material adverse effect on our business, financial condition and results of operations.

Delays in the commencement or completion of clinical trials are common and could result in increased costs to us and delay or limit our ability to generate revenue.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

obtaining regulatory approval to commence a clinical trial;

reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

manufacturing sufficient quantities of a product candidate for use in clinical trials;

obtaining IRB approval to conduct a clinical trial at a prospective site;

recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including

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competition from other clinical trial programs for the treatment of skin cancer or similar indications; and

retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues; and

a lack of adequate funding to continue the clinical trial.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes, which could impact the cost, timing or successful completion of a clinical trial. If we experience delays in the commencement or completion of our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also lead to the denial of regulatory approval of a product candidate.

We depend on clinical investigators and clinical sites to manage our clinical trials and perform related data collection and analysis, which exposes us to potential costs and delays outside our control.

We do not currently conduct clinical trials on our own, and instead rely on CROs to provide us with clinical trial design and administration services, and on independent clinical investigators to provide services in connection with our preclinical pharmacology and toxicology research and development and our clinical trials. Furthermore, in the future we may need to rely on other independent CROs to provide us with clinical trial design and administration services. Our agreements with CROs can generally be terminated by either party upon 30 to 60 days notice. Our preclinical pharmacology and toxicology research and development and our clinical trials are conducted by several third parties at a number of different sites in different jurisdictions, including the United States, Australia and New Zealand, and these third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data. We own no laboratories or other research space and, therefore, must rely on third parties for these services. To date, we have been able to manage the use of these third parties in order to effectively carry out our preclinical pharmacology and toxicology research and development and our clinical trials, despite the fact that these third-parties are not our employees, and we have limited ability to control the amount or timing of resources that they devote to our programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols or regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. In addition, the execution of research and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial attractiveness of any approved product.

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Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities. Furthermore, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw their approval of the product;

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

Additionally, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U.S. Congress, the U.S. Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and changes in regulatory requirements and guidance. If we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues will be delayed.

Even if our products receive regulatory approval, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our products.

Even if we receive regulatory approval for any of our product candidates, potentially costly follow-up or post-marketing clinical trials may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Our product candidates will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, including the FDA s general prohibition against promoting products for unapproved or off-label uses, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we, or a regulatory agency, discover previously unknown problems with a product or the manufacturing facilities of our contract manufacturers, a regulatory agency may impose restrictions on that product, on us or on our third party contract manufacturers, including requiring us to withdraw the product from the market. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters;

impose civil or criminal penalties;

suspend our regulatory approval;

suspend any of our ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications filed by us;

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impose restrictions on our operations, including costly new manufacturing requirements, closing our contract manufacturers facilities or terminating licenses to manufacture cGMP grade material;

impose import or export bans; or

seize or detain products or require us to initiate a product recall.

Any of the foregoing could seriously harm the commercialization of our products and our results of operations may be seriously harmed. Likewise, any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our products.

In addition, the law or regulatory policies governing our products may change. New statutory requirements or additional regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our products, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

We may need significant amounts of additional financing, which may not be available to us on favorable terms, or at all, which raises substantial doubts about our ability to continue as a going concern. If the Merger Agreement is terminated and we fail to obtain additional financing, we may be unable to fund our operations and commercialize our product candidates and may never achieve profitability.

Since inception, we have financed our operations primarily through placements of equity securities. We believe that the loans of up to an aggregate principal amount of US$24 million until the earlier of the completion of the merger between us and LEO or the termination of the Merger Agreement that LEO has agreed to make to us pursuant to the loan agreement, dated September 2, 2009 (the LEO Loan Agreement and together with the GE Loan Agreement, the Loan Agreements), together with our current cash and cash equivalents at June 30, 2009, will be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. Peplin can request no more than one advance under the LEO Loan Agreement in any 15-day period, and each advance cannot exceed the lesser of (a) $2,000,000 and (b) the amount of Peplin s budgeted cash expenditures and transaction expenses for the month, but in no event shall the aggregate principal amount of all outstanding advances exceed the aggregate amount available under the LEO Loan Agreement.

However, in the event that the Merger Agreement is terminated, we will (a) be unable to draw down further funds under the LEO Loan Agreement, (b) have to repay the principal of and interest accrued on the loans previously made to Peplin under the LEO Loan Agreement and (c) in certain circumstances, pay LEO a $10 million break-up fee. If the Merger Agreement is terminated, not only will we need to pay the amounts above, but we will need to raise additional funds to continue operations because our projected cash and cash equivalents will not be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures for such 12-month period or make the required payments under the GE Loan Agreement.

The risk that the Merger Agreement is terminated has caused our independent registered accounting firm to issue an opinion on our consolidated financial statements that states that, in the event the Merger Agreement is terminated, there is substantial doubt about our ability to continue as a going concern.

Given the early stage of product development of our product candidates, we cannot accurately predict the additional funds that will be required to conduct additional research and clinical trials, obtain additional regulatory approvals or to commercially launch any approved products. Our future funding requirements will depend on many factors, including:

whether the merger is completed;

the scope, results, rate of progress, timing and costs of preclinical studies and clinical trials and other development activities;

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the costs and timing of seeking and obtaining regulatory approvals;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs of developing our sales and marketing capabilities and establishing distribution capabilities;

the costs of securing coverage, payment and reimbursement of our product candidates, if any of our product candidates receive regulatory approval;

the effects of competing clinical, technological and market developments; and

the terms, timing and cash requirements of any future acquisitions, collaborative arrangements, licensing of product candidates or investing in businesses, product candidates and technologies.

To meet these capital raising requirements, we may raise funds through a variety of means, including:

public or private equity offerings;

debt financing;

collaborations with pharmaceutical companies; and

license agreements.

If we are not able to secure additional funding in the manners described above when needed, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of one or more of our product candidates.

Raising additional funds by issuing securities, debt financings or through licensing arrangements may cause our stockholders to experience significant dilution in their ownership interest, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders ownership will be diluted. Peplin Limited, our wholly-owned subsidiary, entered into the GE Loan Agreement. The GE Loan Agreement is guaranteed by Peplin, Inc. and each of the subsidiaries of Peplin Limited. The GE Loan Agreement is secured by a pledge of all of our assets other than intellectual property, including the shares of the outstanding capital stock, or other equity interests, of each of our subsidiaries, and contains a variety of operational covenants, including limitations on our ability to incur liens or additional debt, make dispositions, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions and transactions with affiliates, among other restrictions. The rights of LEO pursuant to the LEO Loan Agreement are subordinated to the rights of the lenders under the GE Loan Agreement.

Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations. Peplin and its subsidiaries borrowings under the Loan Agreements or any future debt financing we do will need to be repaid, which creates additional financial risk for us, particularly if our business, or prevailing financial market conditions, are not conducive to paying-off or refinancing our outstanding debt obligations. Furthermore, our failure to comply with the covenants in the Loan Agreements could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, which could have a material adverse effect on our cash position, business, prospects, financial condition and results of operations.

In addition, to the extent that we raise additional funds through collaborations and licensing agreements, we may have to relinquish valuable rights and controls over our technologies, research programs or products or grant licenses on terms that may not be favorable to us.

Even if our product candidates obtain regulatory approval, they may not be accepted in the marketplace by physicians, patients and the medical community.

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There is a risk that our product candidates, if they receive regulatory approval, may not gain market acceptance among physicians, patients and the medical community. There is a risk that certain doctors and patients will not transition to using our products from currently entrenched therapeutic alternatives. In some cases, such reluctance to transition may not be based on the relative effectiveness of our products as compared to currently available alternatives. The degree of market acceptance of our products may depend on a number of factors, which include:

- timing of marketing introduction and number and clinical profile of competitive products;
- our ability to provide acceptable evidence of safety and efficacy and our ability to secure the support of key clinicians and physicians for our products;
- relative convenience and ease of administration;
- cost effectiveness and pricing compared to existing and new treatments;
- availability of coverage reimbursement and adequate payment from health maintenance organizations and other third-party payers;
- personal preferences for more entrenched therapeutic alternatives;
- the commercial design of our products, including our ability to tailor our products to the specific needs of physicians and patients;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

If we are unable to obtain adequate coverage or reimbursement from third-party payers for PEP005 Gel for AK or PEP005 Gel for BCC, or any other product candidates that we may seek to commercialize, our revenues and prospects for profitability will suffer.

Our lead product is targeted at the treatment of a disease which is most prevalent in older populations, and many patients will not be capable of paying for our products themselves and will rely on third-party payers, such as Medicare, Medicaid and private health insurers, including managed care organizations and other third-party payers, to pay for their medical needs. As such, the commercial success of our product candidates, if approved, will be substantially dependent on whether coverage and reimbursement is available from third-party payers. Importantly, third-party payers in the United States, the European Union, Australia and other jurisdictions are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate payment for our products.

Our products may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Large private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payers, including Medicare, are challenging the prices charged for medical products and services, and many third-party payers limit or delay reimbursement for newly approved health care products. In particular, third-party payers may limit the covered indications. Cost-control initiatives could cause us to decrease the price we might establish for our products, which could result in lower than anticipated product revenues. If the prices for our product candidates decrease or if governmental and other third-party payers do not provide adequate coverage or reimbursement, our prospects for revenue and for profitability will suffer.

Furthermore, many healthcare providers, such as hospitals, receive a fixed reimbursement amount per procedure or other treatment therapy, and these amounts are not necessarily based on the actual costs incurred. As a result, these healthcare providers may choose only the least expensive therapies. We cannot guarantee that our product candidates

will be the least expensive alternative and providers may decide not to use them or buy them for treatment. If reimbursement is not available or is available only to limited

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levels, we may not be able to commercialize our products successfully, or at all, which would harm our business and prospects.

We cannot assure you what type or amount of reimbursement will be available for our PEP005 Gel for AK. If physicians do not receive attractive reimbursement for PEP005 Gel for AK, they may choose to prescribe other treatment alternatives, such as cryotherapy.

We do not expect to advance the application of PEP005 for other indications in the foreseeable future.

We believe that there are other potential uses for PEP005 in topical formulations, such as to treat squamous cell carcinoma, or SCC, and nodular BCC, and as a therapy for certain forms of leukemia and for superficial forms of bladder cancer. While our early preclinical studies and clinical trials have indicated a potential for PEP005 to treat these skin and other cancers, our research and development efforts are at a very early stage for these indications. We do not expect to launch significant clinical trials of these indications in the foreseeable future.

If we are unable to establish sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute our product candidates, our business may be harmed.

We do not have a sales organization and have no experience as a company in the marketing, sales and distribution of our product candidates in the United States or elsewhere. To achieve commercial success for any approved product we must either develop a sales and marketing force or enter into arrangements with others to market and sell our products. Following product approval, we currently plan to establish a direct sales force to market our products in the United States and Australia. Our sales force will be competing with experienced and well-funded marketing and sales operations of competitors. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. The size and cost of the required sales force will depend on a number of future developments including results of clinical trials for PEP005 Gel for AK, the final prescribing information or label content that will dictate the scope of product promotional activities, the competitive environment for products and technologies to treat AK, the size and concentration of the various physician specialties that treat AK, the prescribing habits of those physician specialties and the number of patients seeking treatment for AK. Due to these uncertainties, we cannot currently predict the cost to us of developing such a sales force. In addition, we may not be able to develop this capacity on a timely basis, or at all. If we are unable to establish sales and marketing capabilities, we will need to contract with third parties to market and sell our approved products in these locations. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States or other territories, our product revenue could be lower than if we directly marketed and sold our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

Our success depends in part on our ability to protect our intellectual property. If we are not able to protect our intellectual property, trade secrets and know-how, our competitors may use it to develop competing products.

We have no patent protection for the compound PEP005 itself. Our basic patents are for the use of PEP005 and related compounds in the treatment of certain diseases. As a result, competitors who obtain the requisite regulatory approval may be able to offer products with the same active ingredient as PEP005 so long as they do not infringe any of our use and formulation patents. In total, we own exclusive rights to three patents and seven patent applications in the United States, and 34 patents and 9 patent applications (including one pending Patent Cooperation Treaty application) outside the United States, relating to uses and formulations of PEP005. Our issued U.S. and non-U.S. patents expire between August 2018 and August 2026, subject to any patent term extension which might be available under the Hatch-Waxman

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legislation or similar laws in Europe and other foreign jurisdictions. Of these issued patents and patent applications, four and seven, respectively, relate to the treatment of skin cancers, including SCC and BCC, and pre-cancerous skin lesions, including AK. We also have patents and patent applications related to the treatment of other conditions, including solid cancers, tumors, colon cancer, bladder cancer, prostate cancer, cervical cancer, breast cancer and warts. All of our patents and patent applications relate to technology that we have developed in-house or have exclusive rights to.

The additional risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patent that are issued may not provide meaningful protection or may subsequently be held to be invalid or unenforceable;
- the process by which we make PEP005, which we hold as a trade secret, may become publicly known;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may be able to develop alternative, economically feasible, sources of PEP005, which may be a source of competition for us;
- other companies may challenge patents licensed or issued to us or our industry partners;
- other companies may design around technologies we have licensed or developed; and
- we have limited patent protection outside the United States, which may make it easier for third parties to compete in foreign jurisdictions. Our basic use patents and applications have counterparts in only nine foreign countries and under the European Patent Convention.

We may incur substantial costs in asserting any patent or intellectual property right and defending legal action against such rights. Such disputes could substantially delay our product development or our marketing activities.

In addition to patents and patent applications, we depend upon trade secrets and know-how to protect our proprietary technology. We require all employees, consultants, and collaborators to enter into nondisclosure agreements that prohibit the disclosure of confidential information to any other parties. We require that our employees and consultants disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

We can provide no assurance that third parties will not claim that we have infringed their proprietary rights or that our products or methods will not infringe upon the patents of third parties.

From time to time, we may receive notices of claims of infringement, misappropriation or misuse of other parties proprietary rights. Some of these claims may lead to litigation. There can be no assurance that we will prevail in these actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us. Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management s attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party s patent) to the party claiming infringement, develop non-infringing technology, stop selling or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all.

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Our intellectual property rights may not provide meaningful commercial protection for our products, which could enable third parties to use our technology or methods, or very similar technology or methods, and could reduce our ability to compete.

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. Our patents might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. Further, we cannot guarantee that we will continue to develop our own patentable technologies. We may need to assert claims or engage in litigation to protect our proprietary rights, which could cause us to incur substantial costs, could place significant strain on our financial resources, and could divert the attention of management from our business. We may incur substantial costs in pursuing this litigation and the outcome of this litigation is uncertain. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Although we have taken steps to protect our intellectual property and proprietary technology, we cannot assure you that third parties will not be able to design around our patents. In addition, although we have entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. If our intellectual property does not provide significant protection against competition, our competitors could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

Our manufacturing operations are, in part, dependent on a single source supplier and the loss of this supplier could harm our business.

We rely on a single third-party supplier for the formulation, filling and packaging of our product candidates. Currently, formulation, filling and packaging of our AK product candidates is undertaken by DPT Laboratories, Ltd., or DPT, a contract manufacturing organization in San Antonio, Texas. Pursuant to our development and clinical supply agreement with DPT, DPT is responsible for supplying us with PEP005 Gel for AK in quantities sufficient for our Phase 3 clinical trials. Clinical batches are formulated, filled and packaged under cGMP conditions at DPT s facilities in San Antonio, Texas. The clinical supplies are then shipped to locations designated by us or our clinical research organization for use in trials. Our development and clinical supply agreement with DPT has a four-year term, ending October 2011. We may terminate the agreement for any reason upon thirty days written notice to DPT. DPT may terminate the agreement upon thirty days written notice to us upon our uncured breach or our insolvency. Our reliance on this supplier also subjects us to other risks that could harm our business, including:

increased component costs if DPT raises its prices;

we are not a major customer of DPT, and DPT may therefore give other customers needs higher priority than ours;

we may not be able to obtain adequate supply of PEP005 Gel for AK in a timely manner or on commercially reasonable terms, or at all;

if our supply relationship should be terminated, we may have difficulty locating and qualifying an alternative supplier, which we expect could take a year or longer; and

DPT may encounter financial hardships, which could inhibit its ability to fulfill our orders and meet our requirements.

If we receive regulatory approval, it may become more difficult to quickly establish additional or replacement suppliers, particularly because of the FDA approval process. Any interruption or delay in the

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supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

PEP005 is naturally sourced. We may not be able to ensure quantity and quality of supply.

Plant materials used in the production of botanical drug products often are not completely characterized and defined or are prone to contamination, deterioration and variation in composition and properties. In many cases, the active constituent in a botanical drug is not identified, nor is its biological activity well characterized. Therefore, unlike synthetic or highly purified drug products, it may be difficult to ensure the quality of a botanical drug by controlling only the corresponding drug substance and drug product. If we fail to implement adequate quality and in-process controls during manufacturing and final process validation, we may be unable to adequately ensure the quality of our product candidate and may be unable to obtain approval to market our product candidates. This would have a material adverse effect on our business and our profitability.

The active pharmaceutical ingredient in PEP005 is naturally sourced from southeast Queensland, Australia. Accordingly, supply may be subject to adverse weather conditions and other natural events affecting that region, including droughts and severe storms.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing capabilities are insufficient to produce an adequate supply of products, our growth could be limited and our business could be harmed.

We operate our leased manufacturing facility for the drying, milling, extraction and purification of pharmaceutical grade PEP005. We outsource other manufacturing activities, such as formulation and filling, to a third-party manufacturer. We intend to continue this practice for any future clinical trials and large-scale commercialization of any product candidates that receive regulatory approval and become commercial drugs.

Our ability to develop and commercialize PEP005 Gel for AK, PEP005 Gel for BCC and any other product candidates will depend in part on our ability to arrange for third parties to manufacture our products at a competitive cost, in accordance with strictly enforced regulatory requirements and in sufficient quantities for clinical testing and eventual commercialization. We have not yet manufactured commercial batches of PEP005 Gel for AK or PEP005 Gel for BCC or any of our other product candidates. Third-party manufacturers that we select to manufacture our product candidates for clinical testing or on a commercial scale may encounter difficulties with the small and large-scale formulation and manufacturing processes required for commercialization of our product candidates. Such difficulties could result in delays in clinical trials, regulatory submissions or commercialization of our product candidates. Our inability to enter into and maintain agreements with third-party manufacturers on acceptable terms could cause shortages of clinical trial supplies of our product candidates, thereby delaying or preventing regulatory approval or commercialization of the affected product candidate, and adversely affecting our ability to generate revenue. Once a product candidate is approved and being marketed, we may need to increase our manufacturing capacity by a significant level to meet anticipated market demand. Further, development of large-scale manufacturing processes will require additional validation trials, which the FDA must review and approve. We may not successfully complete any required increase in manufacturing capacity in a timely manner or at all. Even if our products receive regulatory approval, if we are unable to manufacture a sufficient supply, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

If we or our current or future third-party manufacturers fail to comply with FDA, state, local or foreign regulatory requirements, we may be unable to produce our products and our business could suffer.

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We and any current or future third-party manufacturers of our products must comply with strictly enforced cGMP requirements enforced by the FDA through its facilities inspection program. These requirements apply to the manufacture of product candidates for clinical trials, as well as commercially marketed products, and include quality control, quality assurance and the maintenance of records and documentation. We or any current or future third- party manufacturers of our products may be unable to comply with cGMP requirements and with other FDA, state, local or foreign regulatory requirements. We have little control over third-party manufacturers compliance with these regulations and standards. A failure to comply with these requirements by our current or future third-party manufacturers could result in the issuance of warning letters from authorities, as well as sanctions being imposed on us, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure, recall or withdrawal of product approval. In addition, we have limited control over these manufacturers ability to maintain adequate quality control, quality assurance and qualified personnel. If the safety of any quantities supplied by third parties is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for, or successfully commercialize, one or more of our product candidates, and we may be held liable for any injuries sustained as a result, which would harm our business and prospects significantly. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if our current or future manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues.

We operate in a highly competitive industry. Organizations which compete with us may be better resourced and more competitive.

We operate in a highly competitive industry with intense competition coming from more established and better-resourced organizations, as well as from academic institutions, government agencies and private and public research institutions. We are seeking to develop and market products that will compete with other products and drugs that currently exist or are being developed or may be developed in the future.

Currently, there are several types of therapies utilized for the treatment of AK. These include: cryotherapy, an office procedure during which, lesions are destroyed by freezing with liquid nitrogen; PDT, which involves the in-office application of a photosensitizer solution followed by a several hour incubation period and then light therapy to activate the drug and destroy the lesions; and various topical agents such as Efudex, Solaraze, Carac, Fluoroplex and Aldara which are applied by the patient at home. The companies that are developing or marketing topical products for the treatment of AK include Graceway Pharmaceuticals, LLC, Meda AB, iNova Pharmaceuticals (Australia) Pty Limited, Valeant Pharmaceuticals International, Dermik Laboratories and PharmaDerm. Commercial development or marketing of PDT agents for the treatment of AK is currently conducted by a number of companies, including DUSA Pharmaceuticals, Inc., Biofrontera AG, photonamic GmbH & Co. KG, PhotoCure ASA and Galderma.

Many of the companies that we compete against enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payers;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, are less expensive, or that reach the market sooner than our product candidates.

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If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and the privacy and security of individually identifiable health information are or will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the U.S. federal government and the states in which we conduct our business, without limitation. The regulations that may affect our ability to operate include, without limitation:

- the federal anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above U.S. 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, 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 in some cases are not preempted by HIPAA, thus complicating compliance efforts.

There also have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels that will affect our operations. 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 or will, when adopted, apply to us, we may be subject to civil and criminal penalties, including damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. 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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Changes in foreign currency exchange rates could result in fluctuations in our reported financial results.

We are exposed to foreign currency exchange rate risk, particularly with the U.S. dollar, Australian dollar and the British pound, as a result of certain research and development activities that are undertaken internationally. We had foreign currency translation losses in recent periods and may have further losses in the future. On October 1, 2008, we changed our functional currency to the U.S. dollar. Prior to this date our functional currency was the Australian dollar, and our reported results were subject to fluctuation resulting from changes in the Australian dollar to U.S. dollar exchange rate.

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We will need to increase the size of our operations, and we may experience difficulties in managing our growth.

We will need to continue to expand our managerial, operational, financial and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

manage our clinical trials effectively, including our ongoing Phase 3 clinical trial for PEP005 Gel for AK and our ongoing Phase 2 clinical trials for PEP005 Gel for BCC, which are being conducted at numerous clinical trial sites;

manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors, collaborators and other third parties;

continue to improve our operational, financial and management controls, reporting systems and procedures; and

attract and retain sufficient numbers of talented employees.

Any growth may place significant strain on our management and financial and operational resources. If we fail to manage these challenges effectively, our business could be harmed.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results and our overall financial condition.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. During the recent presidential election campaign, the candidates discussed healthcare reform proposals which, if enacted, could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business. With the new presidential administration, there have been, and we expect there will continue to be, legislative and regulatory proposals to reform the healthcare system in ways that could have a material adverse effect on our business.

We may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The Medicare Modernization Act of 2003, or MMA, contains provisions that may change U.S. importation laws and expand consumers ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make the required certification. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the U.S. Customs Service, and other government agencies. For example, Pub. L. No. 109-295, which was signed into law on October 4, 2006 and provides appropriations for the Department of Homeland Security for fiscal year 2007, expressly prohibits the U.S. Customs Service from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug and Cosmetic Act. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own product candidates could negatively impact our business and prospects.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell our product candidates profitably.

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In both the United States and certain foreign jurisdictions, there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the MMA added an outpatient prescription drug benefit to Medicare, a publicly funded health insurance program in the United States generally for the elderly and disabled, which became effective on January 1, 2006. Drug benefits under this new benefit are administered through private plans that negotiate price concessions from pharmaceutical manufacturers. We cannot be certain that our drug candidates will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for our drug candidates, which will be determined by market factors.

The MMA also changed the formula for determining payment for certain drugs provided in physician offices and other outpatient settings. Further, with respect to the Medicaid program, the Deficit Reduction Act of 2005 made changes to certain formulas used to calculate pharmacy reimbursement which could lead to reduced payments to pharmacies. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If our current or future drug candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products.

We may enter into collaborative relationships and conflicts may arise between us and our collaborators that could delay or prevent the development or commercialization of our product candidates.

We may enter into collaborative agreements to develop and commercialize our products. These agreements may require our partners to undertake or fund certain research and development activities, make payments to us on achievement of certain milestones and pay royalties or make profit-sharing payments when and if a product is marketed.

Conflicts may arise between our collaborators and us, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with existing or future collaborators, they may act in their self-interest, which may be adverse to our best interests. In addition, collaborative agreements may be terminable by our industry partners. Suspension or termination of collaborative agreements may have a material and adverse impact on our business, prospects, financial condition and results of operations.

A loss of key executives or failure to attract qualified personnel could limit our growth and adversely effect our business.

Our future success depends in part on the continued service of our executive officers, including, in particular, Mr. Wiggans and Dr. Welburn. Although we have entered into employment agreements with each of our executive officers, including, Mr. Wiggans and Dr. Welburn, we employ these individuals on an at-will basis and their employment can be terminated by us or them at any time, for any reason, with notice. The notice requirements for termination range from one month to three months. In addition, we do not have key person insurance on any of our executives. The loss of any one or more of our executive officers could place a significant strain on our remaining management team and would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Furthermore, our future growth will depend in part upon our ability to identify, hire and retain additional key personnel, including qualified management, research and other highly skilled technical personnel. Competition for such skilled personnel is intense, and the loss of services of a number of key individuals, or our inability to hire new personnel with the requisite skill sets, could harm and/or delay our research and development programs, including the commercialization of some or all of our product candidates.

We use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

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We use hazardous materials, such as ethanol, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local, including Australian, laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our drug development efforts.

In addition, we cannot entirely eliminate the risk of accidental injury from improper use of our products or otherwise or from contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers compensation insurance policy. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could significantly exceed our insurance coverage, which is limited to $4,052,000 for pollution cleanup, and we are uninsured for third-party contamination injury. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We face costs associated with importing our products into markets outside of Australia and our business may become subject to economic, political, regulatory and other risks associated with international operations.

The cultivation of the plants extracted for use in our product candidates is substantially undertaken in southeast Queensland, Australia. As much as our product is likely to be manufactured in Australia, we may face difficulties in importing our products into various jurisdictions as a result of, among other things, import inspections, incomplete or inaccurate import documentation or defective packaging. There may be significant costs associated with importing and exporting our product.

In addition, our business is subject to risks associated with conducting business internationally, in part due to our suppliers being located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

difficulties in compliance with non-U.S. laws and regulations;

changes in non-U.S. regulations and customs;

changes in non-U.S. currency exchange rates and currency controls;

changes in a specific country s or region s political or economic environment;

trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non U.S. governments; and

negative consequences from changes in tax laws.

If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and damage to our reputation.

Our clinical trials might potentially expose us to product liability claims in the event our products in development have unexpected effects on subjects. In addition, if any of our products are approved for sale, we may face exposure to claims by an even greater number of persons than were involved in the clinical trials once we begin marketing, distribution and sales of our products commercially.

Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products;

injury to our reputation;

suspension of our clinical trials;

withdrawal of clinical trial participants;

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costs of related litigation;

substantial monetary awards to patients and others;

loss of revenues; and

the inability to commercialize our products.

We maintain a group of insurance policies covering our global clinical trial programs of up to approximately $10 million per occurrence annually. Although we believe that our existing policies are adequate, we cannot assure you that our insurance would fully protect us from the financial impact of defending against any product liability claim. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future.

Our compliance efforts may not be sufficient to meet the rules of the Securities Exchange Act of 1934, as amended, or the Australian Securities Exchange, subjecting us to liability, fines and lawsuits.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), and expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place undue strain on our personnel, systems and resources. The shares of our common stock are publicly traded on the Australian Securities Exchange, or the ASX, in the form of CHESS Depositary Interests, or CDIs. As a result, we must comply with the ASX Listing Rules. We have policies and procedures that we believe are designed to provide reasonable assurance of our compliance with the Exchange Act and the ASX Listing Rules. If, however, we do not follow those procedures and policies, or they are not sufficient to prevent non-compliance, we could be subject to liability, fines and lawsuits.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be adversely affected.

In connection with our September 30, 2008 quarterly filing, we, together with our independent registered public accounting firm, identified a material weakness in our internal controls over financial reporting. A material weakness is a control deficiency, or a combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or deterred. Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during such periods in accordance with the provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses.

The material weakness related to our period end close process and specifically the accrual process and resulted in the recording of a material adjustment in the three month period ending September 30, 2008.

We have taken remedial measures to improve the effectiveness of our internal controls including engaging our independent registered public accounting firm to review and test our current internal controls and provide recommendations for improvements to these internal controls processes, providing additional training to existing personnel and improving internal review processes regarding accruals and the period end close process. As a result of these measures we believe that the material weakness previously identified has been remediated.

We plan to continue to assess our internal controls and procedures and intend to take further action as necessary or appropriate to address any other matters we identify, including to effect compliance with Section 404 of the Sarbanes-Oxley Act when we are required to make an assessment of our internal controls under Section 404 which is anticipated to be for our 2010 fiscal year.

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The existence of a material weakness is an indication that there is a more than remote likelihood that a material misstatement of our financial statements will not be prevented or detected in a future period while that material weakness continues to exist. The process of designing and implementing effective internal controls and procedures is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. We cannot assure you that we will implement and maintain adequate controls over our financial processes in the future. In addition, we cannot assure you that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

We cannot assure you that these or other material weaknesses or significant deficiencies in our internal controls will not be discovered in the future. If we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company and we may not be able to provide a report on the effectiveness of our internal controls. Any failure by us to timely provide the required financial information or provide a report on the effectiveness of our internal controls could materially and adversely impact our financial condition and the market value of our securities.

Risks Related To Our Common Stock

Our holding company structure makes us dependent on our subsidiaries for our cash flow and subordinates the rights of our stockholders to the rights of creditors of our subsidiaries in the event of an insolvency or liquidation of any of our subsidiaries.

We are a holding company and, accordingly, all of our operations are conducted through our subsidiaries. Our subsidiaries are separate and distinct legal entities. As a result, our cash flow in the future may depend upon the earnings of our subsidiaries. The ability of our subsidiaries to provide us with funds may be limited by other obligations. In addition, we depend on the distribution of earnings, loans or other payments by our subsidiaries to us. Our subsidiaries have no obligation to provide us with funds for our payment obligations. If there is an insolvency, liquidation or other reorganization of any of our subsidiaries, our stockholders will have no right to proceed against their assets. Creditors of those subsidiaries will be entitled to payment in full from the sale or other disposal of the assets of those subsidiaries before we, as a shareholder, would be entitled to receive any distribution from that sale or disposal.

We will incur significant increased costs as a result of having to comply with the Exchange Act and the Sarbanes-Oxley Act and maintaining listing on the ASX, and as a result of the increasing complexity of our business as we grow and execute our strategies.

The Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or the SEC, have imposed various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We will need to continue to devote a substantial amount of time to such compliance activities. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more costly. Furthermore, we expect to incur additional costs related to implementation of suitable finance and accounting systems, procedures and controls as we grow.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls over financial reporting and disclosure controls and procedures. In particular, for our fiscal year ending June 30, 2010, we will need to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of, and to allow our auditors to provide an attestation as to the effectiveness of our internal controls over financial reporting for that fiscal year, as required by Section 404 of the Sarbanes-Oxley Act. As a result of our compliance with Section 404, we will incur substantial accounting expense, expend significant management efforts and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to ensure such compliance.

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Our CDIs are listed on the ASX. As a result, we will be subject to ongoing listing and other requirements under the ASX. We are also subject to the reporting requirements of the Exchange Act. Compliance with the ongoing listing requirements of the ASX and the reporting requirements of the Exchange Act can be expensive and time consuming and may cause us to incur ongoing additional expenses.

We have never paid a dividend and we do not intend to pay dividends in the foreseeable future which means that stockholders may not receive any return on their investment from dividends.

We have never declared or paid any cash dividends on shares of our common stock and we do not anticipate paying any cash dividends in the foreseeable future. Dividends may only be paid out of our profits, and will depend upon our results of operations, financial condition, current and anticipated cash needs, contractual restrictions, restrictions imposed by applicable law and such other factors that our board of directors deems relevant. Furthermore, our loan agreement prohibits us from paying cash dividends. Any future determination to pay cash dividends will be at the discretion of our board of directors and would require the consent of the lenders in accordance with the terms of our loan agreement. As a result, capital appreciation, if any, of our common stock will be our stockholders only source of gain.

Resale of our common stock may be difficult because there is not an active trading market for our shares in the United States, and it is possible that no market in the United States will develop. This may reduce or limit the potential value of our shares.

Although our CDIs are traded on the ASX, there is not currently an active trading market for our shares of common stock in the United States, and there is no assurance that such a public market will develop in the future. Even in the event that a public market does develop, there is no assurance that it will be maintained or that it will be sufficiently active or liquid to allow stockholders to easily dispose of their shares. The lack of a public market or the existence of a public market with little or no activity or liquidity is likely to reduce or limit the potential value of our common stock.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We maintain our headquarters in Emeryville, California, in leased facilities consisting of approximately 9,000 square feet. The lease for our Emeryville facility expires in August 2012, with one option to extend for an additional three-year term. We also lease offices in Newstead, Australia and a manufacturing facility in Southport, Queensland, Australia. We recently entered into a new lease in Newstead of approximately 7,550 square feet, pursuant to a lease that expires in April 2016 with no option of extension. Our manufacturing facility in Southport consists of approximately 6,000 square feet, pursuant to a lease that expires in May 2012, with one option to extend for an additional five-year term.

We believe that our existing facilities are in good condition and suitable for the conduct of our business and that additional space will be available on commercially reasonable terms as needed.

Item 3. ***Legal proceedings***

We are not currently involved in any material legal proceedings.

Item 4. ***Submission of Matters to a Vote of Security Holders***

There were no matters submitted to a vote of our security holders during the fourth quarter of our 2009 fiscal year.

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PART II

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

Market Information

Our common stock is not traded on any United States stock market, but our common stock is traded on the ASX in the form of CDIs under the ASX trading code PLI. The CDIs are convertible at the option of the holders into shares of our common stock on a 1-for-20 basis. The following table sets forth, for the periods indicated, the range of high and low sale prices of our common stock, as reported by the ASX.

	Denominated in Australian Dollars		Denominated in United States Dollars [1]	
	High	**Low**	**High**	**Low**
Year Ended June 30, 2009				
Qtr 1: 09/30/2008	$ 9.78	$ 5.51	$ 8.54	$ 4.81
Qtr 2: 12/31/2008	$ 6.32	$ 3.76	$ 5.52	$ 3.28
Qtr 3: 03/31/2009	$ 8.90	$ 4.65	$ 7.77	$ 4.06
Qtr 4: 06/30/2009	$11.40	$ 7.90	$ 9.95	$ 6.90
Year Ended June 30, 2008				
Qtr 1: 09/30/2007	$16.95	$12.71	$14.80	$11.09
Qtr 2: 12/31/2007	$16.92	$12.65	$14.77	$11.04
Qtr 3: 03/31/2008	$15.59	$ 9.06	$13.61	$ 7.91
Qtr 4: 06/30/2008	$10.19	$ 6.98	$ 8.89	$ 6.09

[1] The prices of our common stock, denominated in United States dollars, is calculated by using the exchange rate as of the close of business on September 21, 2009 of A$1.00 to US$0.8729.

As of September 18, 2009, there were approximately 100 holders of record of our common stock and 3,496 holders of record of our CDIs.

Dividends

We have never paid or declared any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future payment of dividends to our stockholders will depend on decisions that will be made by our board of directors and will depend on then existing conditions, including our financial condition, contractual restrictions, capital requirements and business prospects.

The merger agreement prohibits us from paying or declaring any dividends on our common stock without the prior written consent of LEO.

Unregistered Sales of Equity Securities and Use of Proceeds

On October 16, 2008, we issued 819,378 shares of our common stock to the stockholders of Neosil, Inc., a privately-held dermatology-focused company, in exchange for all of the outstanding shares of Neosil, in connection of our acquisition of that company. The number of shares issued was based on Neosil s estimated fair value of $6.7 million. The shares issued in the acquisition were exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act.

On October 23, 2008, we issued 3,980,259 shares of our common stock to institutional investors at a price of $6.05 per share, and warrants to purchase 1,326,753 shares of our common stock, to raise $24,067,380. For each three shares of common stock acquired, investors received a warrant to purchase one

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share of common stock. The shares and warrants issued in the private placement were exempt from registration under the Securities Act pursuant to Regulation S and Section 4(2) of the Securities Act. We are using the net proceeds for general corporate purposes, including our clinical development program, working capital and operating expenses.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during our 2009 fiscal year.

Item 6. ***Selected Financial Data***

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended June 30, 2007, 2008 and 2009 and for the period from inception to June 30, 2009, and the consolidated balance sheet as of June 30, 2008 and 2009, from our consolidated financial statements included elsewhere in this Form 10-K. We derived the audited consolidated statements of operations data for each of the two years ended June 30, 2005 and 2006, and audited consolidated balance sheet data as of June 30, 2005, 2006 and 2007 from our consolidated financial statements not included in this Form 10-K. You should read this financial data in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and accompanying notes, which are included elsewhere in this Form 10-K, and Item 8. Financial Statements and Supplementary Data.

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	Years ended June 30,					Period from inception to June 30, 2009
	2009	2008	2007	2006	2005	
	(Amounts in thousands, except for per share amounts)					
Consolidated Statements of Operations Data:						
Revenues	$ 0	$ 0	$ 0	$ 0	$ 5,610	$ 5,771
Cost of operations						
Research and development	27,197	19,579	18,238	9,265	7,163	93,054
Sales, general and administrative	16,093	8,089	4,112	2,070	1,657	35,953
Loss from operations	(43,290)	(27,668)	(22,350)	(11,335)	(3,210)	(123,236)
Other income (expenses)	(576)	1,733	1,787	995	472	7,328
Net loss before income tax expense	(43,866)	(25,935)	(20,563)	(10,340)	(2,738)	(115,908)
Income tax expense	(2)	(21)	0	0	0	(23)
Net loss	$ (43,868)	$ (25,956)	$ (20,563)	$ (10,340)	$ (2,738)	$ (115,931)
Net loss per share [1]						
Basic and diluted	$ (3.22)	$ (2.57)	$ (2.31)	$ (1.74)	$ (0.62)	
Shares used to compute net loss per share						
Basic and diluted	13,645	10,097	8,902	5,946	4,388	

(1) Please see Note 1 to our consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per share of common stock.

	Years ended June 30,				
	2009	2008	2007	2006	2005
	(Amounts in thousands, except for per share amounts)				
Balance sheet data:					
Cash and cash equivalents	$ 17,751	$ 25,231	$ 20,246	$ 16,840	$ 6,244
Working capital	2,478	21,530	17,211	14,781	5,102
Total assets	23,364	35,969	24,088	25,314	7,777
Non-current liabilities	4,048	9,336	102	62	0
Stockholders equity	1,858	16,215	19,737	16,385	6,506

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Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

This Management s Discussion and Analysis of Financial Condition and Results of Operations is intended to assist in understanding and assessing the trends and significant changes in our results of operations and financial condition. Historical results may not indicate future performance. This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are often identified by the use of words such as may, will, expect, believe, anticipate, intend, could, estimate, or continue, and similar expressions or variatio forward-looking statements, which reflect our current views about future events, are based on assumptions and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those contemplated by these statements. As used in this Management s Discussion and Analysis of Financial Condition and Results of Operations, the words, we our and us refer to Peplin, Inc. and its consolidated subsidiaries. This Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our consolidated financial statements and related notes included in this report.

Overview

To date we have not generated any revenue from the sale of our products and have funded our operations primarily through the sale of equity securities, the entrance by Peplin Limited, our wholly-owned subsidiary, into a $15 million loan agreement and government grants. We have experienced net losses in each year since our inception. As of June 30, 2009, we had an accumulated deficit of $115.9 million. We expect our net losses to continue and to increase as the continued development of our PEP005 product candidates will require significant additional expenditures for a variety of activities, including continued clinical trials, research and development, manufacturing development, regulatory approvals and the establishment of sales and marketing. We do not expect to generate revenue from the sale of our products until one or more of our product candidates are approved for sale by the FDA, which we do not expect to occur prior to 2011. We cannot assure you that any of our product candidates will obtain FDA approval in a timely manner, or at all. Our product candidates are based on an untested new chemical entity with a novel mode of action.

We may not obtain regulatory approval for many reasons, including, among others:

- our inability to complete our ongoing and planned clinical trials in a timely manner;
- the results of our clinical trials may not effectively demonstrate the safety and efficacy of our product candidates;
- the data from our clinical trials may not support an NDA;
- the FDA may disagree with the results of our clinical trials; or
- the FDA may change its approval policies and procedures.

If we are unable to obtain regulatory approval of any of our product candidates, we will be unable to generate revenue and may never become profitable.

In October 2007, we reorganized our corporate structure. Peplin Limited, formerly known as Peplin Biotech Ltd., was formed in 1999 as an Australian company. On October 16, 2007, we acquired all the outstanding shares of Peplin Limited pursuant to a Scheme of Arrangement. We refer to this transaction as the Reorganization. Following the Reorganization, Peplin Limited became our wholly-owned subsidiary and our business and operations consisted solely of the business and operations of Peplin Limited and our other subsidiaries.

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Fiscal Year

We report results of our operations on a fiscal year basis ending on June 30 of each year. For presentation purposes, we refer in this Form 10-K and the accompanying financial information to a fiscal year end for each year ending June 30.

Critical Accounting Estimates and Judgments

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making assumptions about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies are critical to the process of making significant estimates and judgments in preparation of our financial statements.

Revenue Recognition

The Company applies the revenue recognition criteria outlined in the SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and Emerging Issue Task Forces (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. In applying these revenue recognition criteria, the Company considers a variety of factors in determining the appropriate method of revenue recognition under its revenue arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

The Company s license fee revenues consist of amounts received under a license and collaboration agreement with Allergan entered into in November 2002. License fee revenues include a non-refundable upfront payment, quarterly installment payments and subsequent milestone payments based on performance. Upon receipt, all such payments, including the milestone payments which the Company deems to be inseparable from the overall license fee, are recorded as deferred license fee income and are recognized as revenue ratably over the term of the license. The license and collaboration agreement also provides for certain cost sharing of research and development activities performed by Peplin for which Allergan reimbursed Peplin $234,505 during the 2005 financial year which is reflected in research and development expense in the accompanying statement of operation. This agreement was cancelled in October 2004 and Allergan paid a cancellation fee of $1,332,076 which was recognized as license fee revenue. Pursuant to a termination agreement, Allergan may receive certain future royalties from Peplin (refer to Note 9 for further details). Additionally, all amounts that had been recorded as deferred license fee income at the date of cancellation were recognized as license fee revenue at that time.

Government Grant Income

Government grants, which support the Company s research efforts in specific projects, generally provide for reimbursement of approved costs incurred. Grant receipts are recognized as income when research and development expenditure to which the particular grant relates have been incurred.

The Company has received two grants under the Australian Government s R&D START program, as described in Note 9(d), where the grant payments were made quarterly in advance based on estimated expenditures. In these instances, the advance payments received are classified as deferred income until the qualified expenditures have been incurred. The final START grant was completed in August 2004 and the

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Company is no longer entitled to funding under this grant. There are no unfulfilled conditions or contingencies attaching to this grant nor are there any repayment provisions.

In 2006, the Company was awarded a research grant under the Australian Government s Pharmaceuticals Partnerships Program, or the P3 Program, pursuant to which we entered into a Pharmaceuticals Partnerships Program Funding Agreement, or P3 Agreement. Under the terms of the P3 Agreement, the Company receives grant proceeds in arrears. Where qualifying expenses have been incurred and grant proceeds not yet received, a receivable for grant income is recorded in the balance sheet. The total amount recognized under the P3 Agreement for the years ended June 30, 2007, 2008 and 2009 was $179,752, $1,369,013 and $586,660, respectively. This grant was completed at June 30, 2009; therefore apart from the current grant income receivable for expenditures incurred to June 30, 2009, the Company is no longer entitled to funding under this grant. There are no unfulfilled conditions or contingencies attaching to this grant nor are there any repayment provisions.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements using the fair value based method as prescribed in accordance with the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123R, *Accounting for Stock Based Compensation (revised 2004)* (SFAS 123R). The Company has applied the measurement and valuation provisions of SFAS 123R for all stock options granted since the Company s inception. Stock based compensation expense for employees are measured at the grant date, based on the fair value of the award and is recognized as an expense over the period awards are expected to vest. Under the provisions of SFAS 123R, employee stock compensation is estimated using the Black-Scholes option-pricing model. The Black-Scholes option pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are the estimates of the expected term of the award and the expected volatility of the market price of the Company s stock. The Company uses the simplified method to estimate expected life as it does not have sufficient historical exercise history.

For those options issued prior to June 30, 2006, the Company has utilized an average volatility based on ASX listed guideline companies within the biotechnology sector as there was insufficient company trading history in order to determine an accurate volatility rate. For options issued subsequent to June 30, 2006 through to the date of the Reorganization, the Company calculated expected volatility based on the Company s own trading activity data. Upon the Reorganization, primarily due to the underlying security changing from an Australian ordinary share to U.S. common stock, volatilities are based on NASDAQ-listed peer companies within the biotechnology sector. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on historical experience. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results differ from the Company s estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

Options granted to consultants and other non-employees are accounted for in accordance with EITF consensus No. 96-18, *Accounting for Equity Instruments that are issued to Other than Employees for Acquiring, or in Connection with Selling Goods or Services*. Compensation costs for stock options granted to non-employees are measured at the earlier of the date at which the commitment for performance to earn the equity instrument or the date at which the counterparty s performance is complete. The fair value of stock options, as calculated using a Black-Scholes option valuation model, are expensed over the performance period and are subject to remeasurement over their vesting terms.

Income Tax

The Company accounts for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). SFAS 109 requires recognition of deferred tax assets and liabilities for the estimated future tax consequences of events attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases as well as operating loss and tax credit carry forwards. 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 are expected to be

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recovered or settled. The effect of deferred tax assets and liabilities of a change in tax rates is recognized in the income statement in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48) on July 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

Financial Overview

Revenue

From our inception to June 30, 2009, our revenue consisted of $5.8 million in license fees received under a license and collaboration agreement with Allergan, entered into in November 2002. License fees included a non-refundable upfront payment, quarterly installment payments and milestone payments based on achieving certain predefined milestones. Upon receipt, all such payments, including the milestone payments which we deemed to be inseparable from the overall license fee, were recorded as deferred license fee income and were recognized as revenue ratably over the term of the license. The agreement was cancelled in October 2004 and Allergan paid a fee of $1.3 million, which was recognized as revenue in the year ended June 30, 2005. At that time, all amounts previously recorded as deferred income that had not been recognized were recognized as revenue. We have earned no revenue since the year ended June 30, 2005.

Research and Development Expenses

Our research and development expenses primarily consist of expenses related to the development of products containing PEP005, including preclinical studies, toxicology, clinical trials, regulatory expenses, and manufacturing materials used in clinical trials and other trials. Our expenses to operate our clinical trials include trial design, clinical site reimbursement, data management and associated travel expenses. Our research and development expenses also include fees for design services, contractors and materials, expenses associated with clinical trial materials and employee compensation, including stock-based compensation. From our inception through June 30, 2009, we have incurred $93.1 million in research and development expenses relating primarily to the development of PEP005, net of $1.3 million in product development income received from Allergan. Our license and collaboration agreement with Allergan also provided for Allergan to reimburse us for a portion of the costs of research and development activities performed by us. These amounts were recorded in research and development expense as income.

Sales, General and Administrative

Our sales, general and administrative expenses primarily consist of compensation for our executive, commercial, financial, and administrative personnel, including stock-based compensation, as well as compensation for our board of directors. Other sales, general and administrative expenses include facility costs not otherwise included in research and development expenses, and professional fees for legal, consulting and accounting services.

Other Income (Expense)

Total other income consists of grants received from the Australian government under a number of grant arrangements, including its R&D START program and the P3 Program. These grants support our research efforts in specific projects, and generally provide for reimbursement of approved costs incurred. Grant receipts are recognized by us as other income when research and development expenditures to which the particular grant relates have been incurred.

Our most recent R&D START grant was completed in August 2004. Total income to-date recognized under the R&D START grants was $2.1 million. The amount recognized under the P3 Program from

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inception to June 30, 2009 was $2.6 million. Total other income also consists of interest income earned on our cash and cash equivalents and short-term deposits, as well as interest expense incurred on our loan.

Income Taxes

Since inception, we have incurred operating losses and, accordingly, have not recorded a provision or benefit for income taxes for any of the periods presented.

At June 30, 2009 the Company had gross operating tax loss carry forwards of approximately $22,440,582 (June 30, 2007: $19,278,609 and June 30, 2008: $31,140,389), which may be adjusted if the Company is unable to comply with the recognition criteria for carry forward tax losses under Australian, U.S. or Irish taxation laws. The Company is continuously assessing compliance with the relevant recognition rules as tax laws change and business transactions occur. $16,272,892 of the Company s net operating tax loss carry forwards as of June 30, 2009 are attributable to 2002-2009 tax losses generated within the Company s Australian tax consolidated group, and can be carried forward indefinitely. Pursuant to Australian tax law, tax losses may not be available and would thus be derecognized where there has been a greater than 50% change in the cumulative ownership of the Company combined with a change in the Company s business or capital structure. Presently, there is no knowledge of the Company s 2002-2009 tax losses being at risk of derecognition based on past cumulative changes in ownership. As a result of these tax loss carry forwards, the Company has significant deferred tax assets, however due to the Company s lack of earnings history, realization of these deferred tax assets is not more likely than not, therefore the deferred tax assets have been fully offset by a valuation allowance.

Results of Operations

Comparison of Years Ended June 30, 2009 and 2008

Revenue. We recorded no revenue for the years ended June 30, 2009 and 2008.

Research and Development Expenses. Research and development expenses increased 39% from $19.6 million in the year ended June 30, 2008 to $27.2 million in the year ended June 30, 2009. The increase in the year ended June 30, 2009 was due primarily to the commencement of Phase 3 clinical trials for our lead product PEP005 Gel for AK and a significant increase in the total number of patients treated in these trials as compared to the year ended June 30, 2008. We expect research and development expenses to remain stable over the next financial year as we complete our Phase 3 program for PEP005 Gel for AK.

Research and development expenses represented 71% of total operating expenses for the year ended June 30, 2008 and 63% for the year ended June 30, 2009. We expect research and development expenses to remain relatively stable as we complete our Phase 3 program for PEP005 Gel for AK and continue our ongoing Phase 2 clinical trial for PEP005 Gel for BCC. We do not expect to commence our Phase 3 clinical program for PEP005 Gel for BCC before calendar 2010.

Sales, General and Administrative Expenses. Sales, general and administrative expenses increased 99% from $8.1 million in the year ended June 30, 2008 to $16.1 million in the year ended June 30, 2009. The increase was predominantly due to foreign exchange losses incurred on U.S. dollar denominated debt and deposits held by our Australian subsidiary, Peplin Ltd, an increase in market research activities during the year and an increase in stock based compensation expense. We expect sales, general and administrative costs to increase in future as we begin to expand our commercial, sales and marketing functions.

Other Income (Expense). We had total other income of $1.7 million for the year ended June 30, 2008 and total other expense of $(0.6) million for the year ended June 30, 2009. We received $0.6 million related to government grants during the year ended June 30, 2009 compared to $1.4 million received during the year ended June 30, 2008. Interest expense on our loan increased to $1.8 million during the year ended June 30, 2009, from $1.2 million expensed during the year ended June 30, 2008. We received interest income of $0.6 million during the year ended June 30, 2009 compared to $1.5 million received during the year ended June 30, 2008.

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Comparison of Years Ended June 30, 2008 and 2007

Revenue. We recorded no revenue for the years ended June 30, 2009 and 2008.

Research and Development Expenses. Research and development expenses increased 7% from $18.2 million in the year ended June 30, 2007 to $19.6 million in the year ended June 30, 2008. The increase in the year ended June 30, 2008 was due primarily to the establishment of medical affairs and regulatory affairs in our U.S. office and increased activity in these areas.

Research and development expenses represented 82% of total operating expenses for the year ended June 30, 2007 and 71% for the year ended June 30, 2008. We expect research and development expenses to continue to increase at a greater rate as we devote substantial resources to research and development to support the continued development of our product candidates, including the commencement of our Phase 3 clinical trial program for PEP005 Gel for AK in non-head applications in the third calendar quarter of 2008 and for head applications in 2009 and the continuation of our ongoing Phase 2b clinical trial of PEP005 Gel for AK and Phase 2 clinical trial for PEP005 Gel for BCC. We also intend to expand our research and development efforts and to expand our manufacturing development.

General and Administrative Expenses. General and administrative expenses increased 97% from $4.1 million in the year ended June 30, 2007 to $8.1 million in the year ended June 30, 2008. The increase was due to non-recurring implementation costs of our company reorganization in October and increased staff and overheads necessary to manage and support our growth, particularly in connection with medical affairs, regulatory and commercial functions in our U.S. office.

We expect that our general and administrative expenses will increase in absolute dollar amounts as we continue our efforts to expand our infrastructure and as we incur additional costs in operating as a U.S. company.

Other Income (Expense). Total other income was $1.8 million for the year ended June 30, 2007 and $1.7 million for the year ended June 30, 2008. We recognized income of $0.2 million and $1.4 million related to government grants during the years ended June 30, 2007 and 2008, respectively. Other income for the year ended June 30, 2008 was partially offset by interest expense on our loan of $1.2 million for the year ended June 30, 2008. We incurred no interest expense for the year ended June 30, 2007.

Liquidity and Capital Resources

Since inception through June 30, 2009, the Company has financed its operations primarily through placements of equity securities, receiving aggregate net proceeds from such placements totaling $104.5 million, the entrance by Peplin Limited, our wholly-owned subsidiary, into a $15 million loan agreement, license revenue totaling $5.8 million and Australian government grants totaling $4.7 million. As of June 30, 2009, we had $17.8 million in cash and cash equivalents. Our cash and cash equivalents are held in a variety of interest-bearing instruments, including term deposits with Australian banks with maturities from purchase date of three months or less. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation.

Net cash used in operating activities was $28.4 million, $26.3 million and $17.5 million in the years ended June 30, 2009, 2008 and 2007, respectively. The net cash used in each of these periods primarily reflects net losses for these periods, offset in part by depreciation, non-cash stock-based compensation and non-cash changes in operating assets and liabilities.

Net cash provided by (used in) investing activities was $5.7 million, $(0.8) million and $(0.7) million in the years ended June 30, 2009, 2008 and 2007, respectively. Investing activities in fiscal year 2009 consisted primarily of the acquisition of Neosil and proceeds on maturity of available-for-sale securities. We expect to continue to make investments in the purchase of plant and equipment to support our expanding operations.

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Net cash provided by financing activities was $17.9 million, $28.8 million and $18.8 million in the years ended June 30, 2009, 2008 and 2007 respectively. Cash provided by financing activities consisted primarily of proceeds from the sale of our shares, and repayment of borrowings under the $15 million loan agreement entered into by Peplin Limited, our wholly-owned subsidiary.

On December 28, 2007, Peplin Limited, our wholly-owned subsidiary, entered into the GE Loan Agreement. The GE Loan Agreement is guaranteed by us and each of our subsidiaries. The GE Loan Agreement fully amortizes over a series of thirty-six monthly payments. Under the GE Loan Agreement, we are required to make three monthly payments of interest only, followed by thirty-three monthly payments of principal and interest. Interest accrues on amounts outstanding under the GE Loan Agreement at a fixed per annum rate of 8.50%. The loan is secured by a first-priority security interest in all of our assets (other than intellectual property), including the shares of outstanding capital stock, or other equity interests, of each of our subsidiaries. In addition, we are prohibited from incurring any liens, claims or encumbrances of any kind on our intellectual property, subject to certain exceptions contained in the GE Loan Agreement. Amounts prepaid under the loan agreement are not subject to a prepayment fee. In addition, upon repayment of the amounts borrowed for any reason, we will be required to pay a completion fee equal to $600,000. Under the terms of the GE Loan Agreement, we are subject to operational covenants, including limitations on our ability to incur liens or additional debt, make dispositions, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions and transactions with affiliates, among other restrictions. As of June 30, 2009, we were in compliance with all covenants. In addition, in consideration for entering into the GE Loan Agreement, we granted GE and Oxford warrants to purchase 39,325 shares and 19,662 shares, respectively, of our common stock at an exercise price of $15.26 per share. These warrants were immediately exercisable and will expire on December 28, 2012.

Effective October 16, 2008, we acquired all of the outstanding shares of Neosil. The agreed purchase price of $6.7 million, which was based on the estimated cash balance of Neosil at the closing, was paid with 819,378 shares of our common stock.

On October 23, 2008, we issued 3,980,259 shares of common stock at $6.05, and warrants to purchase 1,326,753 shares of common stock, to raise $24,067,380. For each three shares of common stock acquired, investors received a warrant to purchase one share of common stock. We incurred total transaction costs of $3,118,806.

In connection with the Merger Agreement, Peplin and LEO entered into the LEO Loan Agreement. Advances on the LEO Loan Agreement (Advances) bear interest at a rate per annum equal to the sum of the applicable one-month London Inter-Bank Offering Rate (LIBOR) for the U.S. dollar plus 2% until the termination of the Merger Agreement, and LIBOR for the U.S. dollar plus 9% thereafter. Peplin can request no more than one Advance in any 15-day period, and each advance cannot exceed the lesser of (a) $2,000,000 and (b) the amount of Peplin s budgeted cash expenditures and transaction expenses for the month, but in no event shall the aggregate principal amount of all outstanding Advances exceed the aggregate amount available under the LEO Loan Agreement. The LEO Loan Agreement is unsecured and loans under the LEO Loan Agreement are subordinated to loans pursuant to the GE Loan Agreement.

We believe that the loans that LEO has agreed to provide pursuant to the LEO Loan Agreement, together with our current cash and cash equivalents at June 30, 2009, will be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, in the event that the Merger Agreement is terminated, we will (a) be unable to draw down further funds under the LEO Loan Agreement, (b) have to repay the principal of and interest accrued on the loans previously made to Peplin under the LEO Loan Agreement and (c) in certain circumstances, pay LEO a $10 million break-up fee. If the Merger Agreement is terminated, not only will we need to pay the amounts above, but we will need to raise additional funds to continue operations because our projected cash and cash equivalents will not be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures for such 12-month period or make the required payments under the GE Loan Agreement.

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The risk that the Merger Agreement is terminated has caused our independent registered accounting firm to issue an opinion on our consolidated financial statements that states that, in the event the Merger Agreement is terminated, there is substantial doubt about our ability to continue as a going concern.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available financial resources sooner than we currently expect. Our forecast of the period of time that our financial resources will be adequate to support operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in Risk Factors, herein. In light of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and commercialism of our products. Our future funding requirements will depend on many factors, including:

whether the merger with LEO is completed;

the scope, results, rate of progress, timing and costs of preclinical studies and clinical trials and other development activities;

the costs and timing of seeking and obtaining regulatory approvals;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs of developing our sales and marketing capabilities and establishing distribution capabilities;

the costs of securing coverage, payment and reimbursement of our product candidates, if any of our product candidates receive regulatory approval;

the effects of competing clinical, technological and market developments; and

the terms, timing and cash requirements of any future acquisitions, collaborative arrangements, licensing of product candidates or investing in businesses, product candidates and technologies.

Such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates and we would be required to delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private equity or debt financing, strategic partnerships or other arrangements. Any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants similar to, or more onerous than, the covenants contained in the Loan Agreements. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

Contractual Obligations and Commitments

Our future contractual obligations at June 30, 2009 were as follows:

		Payments Due By Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(in thousands)		

Long-term debt obligations [1]	$ 8,627,554	$ 5,629,087	$ 2,998,467	$	$
Research and development expenditure [2]	9,125,312	9,078,403	46,909		
Operating lease obligations	3,843,464	668,483	1,526,888	843,122	804,971
Interest obligations on long-term debt	1,268,089	862,400	405,689		
Sales, general and administration	129,223	81,155	48,068		
Total	$ 22,993,642	$ 16,319,528	$ 5,026,021	$ 843,122	$ 804,971

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(1) Represents the GE Loan Agreement.

(2) Represents commitments under clinical trial agreements, preclinical research studies and development obligations.

On October 7, 2004, we entered into a termination and settlement agreement with Allergan in order to terminate the license and collaboration agreement entered into with Allergan in November 2002. Pursuant to the terms of the termination agreement, Allergan paid us $1.3 million in satisfaction of its outstanding obligations under the license and collaboration agreement and retained no residual rights to PEP005. Furthermore, should we relicense PEP005 in a topical formulation to another party, we agree to pay Allergan 25% of any license or similar fees we receive prior to the commercialization of such PEP005 product, subject to a cap of $3.0 million, and 25% of royalties and similar revenue we receive following the commercialization of the product subject to a cap of $4.0 million; however, the combination of pre-commercialization license fees and post-commercialization royalties will not exceed $4.0 million. Alternatively, if we or our affiliates sell PEP005 in a topical formulation for specified indications in the United States, Canada, Mexico and certain other countries, we will pay Allergan up to $4.0 million by way of a 10% royalty on net sales. In no event will our total payments to Allergan under the termination agreement exceed $4.0 million.

Off Balance Sheet Arrangements

We have not engaged in off balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Related Party Transactions

For a description of our related party transactions, see the section of this Form 10-K entitled Certain Relationships and Related Party Transaction.

Recently Issued Accounting Standards

Effective July 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157), on a prospective basis for financial assets and liabilities, which requires that the Company determine the fair value of financial assets and liabilities using the fair value hierarchy established in SFAS 157. In February 2008, the FASB issued FASB Staff Position No. FAS 152-7, *Effective Date of FASB Statement no. 157,* which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. The adoptions of SFAS 157 did not have a material impact on the Company s results of operations and financial condition as of and for the year ended June 30, 2009. See Note 14 of our consolidated financial statements for information and related disclosures regarding the Company s fair value measurements.

In June 2009, the FASB issued Statement No. 165 *Subsequent Events* (Statement 165). Statement 165 requires companies to disclose the period over which subsequent events have been evaluated while also requiring a distinction between recognized and non-recognized subsequent events. Statement 165 is effective for interim or annual financial periods ending after 15 June 2009. The Company determined that Statement 165 did not have a material impact on the Company s consolidated financial statements.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our exposure to market risk is confined to our cash and cash equivalents. We do not hold or issue financial instruments for trading purposes.

Our cash and cash equivalents have maturities of less than three months. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents. As of June 30, 2009, we had cash and cash equivalents of $17.8 million. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on the realized value of our cash equivalents. We do not expect to enter into investments for trading or speculative purposes.

Currently, we are exposed to foreign current exchange rate risk, particularly with the U.S. dollar, Australian dollar and the British pound, as a result of certain research and development activities that are undertaken internationally and our U.S. denominated debt under our loan agreement. It is our policy to minimize the use of financial derivatives and achieve risk mitigation through natural hedges. These natural hedges include the maintenance of U.S. dollar and Australian dollar bank accounts and deposits to primarily facilitate the payment of research and development activities. We do not expect to enter into foreign currency exchange contracts for trading or speculative purposes.

Effective October 1, 2008, we changed our functional currency to the U.S. dollar. The change was made prospectively, and was determined based on the significant changes in economic facts and circumstances that occurred recently, in accordance with SFAS No. 52, *Foreign Currency Translation*. Because our historical functional currency was the Australian dollar, our historical reported financial results were subject to fluctuation resulting from changes in the Australian dollar to U.S. dollar exchange rate.

Item 8. ***Financial Statements and Supplementary Data***

Our consolidated financial statements and notes thereto appear on pages 55 to 94 of this Form 10-K.

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PEPLIN, INC.
(A Development Stage Company)
Report of Independent Registered Public Accountant

The Board of Directors and Stockholders of Peplin, Inc.

We have audited the accompanying consolidated balance sheets of Peplin, Inc. (a development stage company) as of June 30, 2009 and 2008, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended June 30, 2009 and for the period from December 7, 1999 (inception) to June 30, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Peplin, Inc. (a development stage company) at June 30, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended June 30, 2009 and for the period from December 7, 1999 (inception) to June 30, 2009, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, the Company s losses from operations and negative cash flow raise substantial doubt about its ability to continue as a going concern. Management s plans as to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young
Brisbane, Australia
September 28, 2009

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	June 30, 2009	June 30, 2008
Assets:		
Current assets:		
Cash and cash equivalents	$ 17,751,089	$ 25,230,533
Grant income receivable	179,300	169,776
Interest receivable	45,692	131,443
Prepaid expenses	764,484	778,923
Deferred costs		4,655,836
Lease deposits	332,157	
Other current assets	863,099	982,400
Total current assets	19,935,821	31,948,911
Non-current assets:		
Restricted cash	352,891	390,698
Lease deposits	328,646	176,170
Plant and equipment net	2,683,077	2,824,111
Other non-current assets	63,072	629,206
Total non-current assets	3,427,686	4,020,185
Total assets	$ 23,363,507	$ 35,969,096
Liabilities and stockholders equity:		
Current liabilities:		
Trade accounts payable	$ 3,405,613	$ 1,282,542
Accrued research and development	6,394,929	2,024,704
Accrued employee benefits and payroll taxes	1,025,952	779,621
Notes payable	5,629,087	5,163,171
Deferred lease incentive	46,387	
Other accrued expenses	955,993	1,168,397
Total current liabilities	17,457,961	10,418,435
Non-current liabilities:		
Accrued employee benefits and payroll taxes	75,478	48,491
Asset retirement obligation	102,946	74,504
Notes payable	2,998,467	8,612,934
Deferred lease incentive	270,822	
Debt completion fee payable	600,000	600,000
Total liabilities	21,505,674	19,754,364
Commitment and contingencies (Note 9)		

Stockholders equity:		
Preferred stock, $0.001 par value: 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2009 and 2008, respectively		
Common stock, $0.001 par value: 100,000,000 shares authorized; 15,371,121 and 10,341,484 issued and outstanding at June 30, 2009 and 2008, respectively	108,159,574	80,744,288
Class B Common stock, $0.001 par value: 1 share authorized, no shares issued and outstanding at June 30, 2009 and 2008, respectively		
Additional paid-in capital	2,812,200	
Deficit accumulated during development stage	(115,930,501)	(72,062,843)
Accumulated other comprehensive income	6,816,560	7,533,287
Total stockholders equity	1,857,833	16,214,732
Total liabilities and stockholders equity	$ 23,363,507	$ 35,969,096

See accompanying notes to financial statements.

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended June 30,			For the period from inception (December 7, 1999) to June 30, 2009
	2009	2008	2007	
License fee revenues	$	$	$	$ 5,770,510
Cost of operations:				
Research and development	27,196,902	19,578,667	18,237,691	93,053,421
Sales, general and administrative	16,092,777	8,088,970	4,112,192	35,953,183
Total cost of operations	43,289,679	27,667,637	22,349,883	129,006,604
Loss from operations	(43,289,679)	(27,667,637)	(22,349,883)	(123,236,094)
Other income (expenses):				
Interest income	583,909	1,540,748	1,537,676	5,168,939
Interest expense	(1,762,606)	(1,219,221)		(3,001,961)
Grant income	586,660	1,369,013	238,404	4,905,795
Other income	15,792	41,435	10,446	255,140
Total other income (expenses)	(576,245)	1,731,975	1,786,526	7,327,913
Net loss before income tax expense	(43,865,924)	(25,935,662)	(20,563,357)	(115,908,181)
Income tax expense	(1,734)	(20,586)		(22,320)
Net loss	$ (43,867,658)	$ (25,956,248)	$ (20,563,357)	$ (115,930,501)
Net loss per share basic and diluted	$ (3.22)	$ (2.57)	$ (2.31)	
	13,644,826	10,096,957	8,902,396	

Weighted average common stock outstanding used in calculation of net loss per share basic and diluted	

See accompanying notes to financial statements.

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Number of shares of common stock	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
Balance at inception (December 7, 1999)						
Issuance of common stock in exchange for the net assets of the Peplin Unit Trust on December 10, 1999	117,672	$ 314,644				$ 314,644
Issuance of common stock at $27.60 per share on December 10, 1999, net of share issue costs	39,329	1,085,233				1,085,233
Buy-back and cancellation of common stock at $22.60 per share on December 10, 1999	(53,000)	(1,199,484)				(1,199,484)
Issuance of common stock at $23.40 per share on January 15, 2000, net of share issue costs	10,414	232,355				232,355
Share split (1 for 15.732 shares) on June 30, 2000	1,685,586					
Fair value of stock options issued to directors & employees during 2000 (post-split date)		57,504				57,504
Issuance of common stock at $4.40 per share on September 18, 2000, net of share issue costs	875,000	3,455,591				3,455,591
Fair value of stock options issued to directors and employees during 2001 and the expense related to options issued in prior years		36,220				36,220
Fair value of stock options issued to non-employees during		120,552				120,552

2001			
Issuance of common stock for services rendered at $9.20 per share on November 5, 2001, net of share issue costs	7,500	69,059	69,059
Share options exercised on October 17, 2001	1,500	6,167	6,167
Share options exercised on November 14, 2001	7,500	31,116	31,116

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Number of shares of common stock	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
Share options exercised on March 18, 2002	500	2,098				2,098
Fair value of stock options issued to directors & employees during 2002 and the expense related to options issued in prior years		100,887				100,887
Fair value adjustment of stock options issued to non-employees in 2001		(25,729)				(25,729)
Fair value of stock options issued for services rendered during 2002		6,204				6,204
Issuance of common stock at $6.80 per share on September 4, 2002, net of share issue costs	336,500	2,264,071				2,264,071
Issuance of common stock at $9.40 per share on June 10, 2003, net of share issue costs	250,000	2,178,856				2,178,856
Share options exercised on August 7, 2002	1,250	5,363				5,363
Share options exercised on August 12, 2002	500	2,157				2,157
Fair value of stock options issued to directors & employees during 2003 and the expense related to options issued in prior years		74,606				74,606
Fair value of stock options issued for services rendered during 2003		99,135				99,135
Issuance of common stock at $12.40 per share on October 9, 2003, net of share issue costs	50,000	605,440				605,440

Issuance of common stock at $12.40 per share on October 24, 2003, net of share issue costs	275,000	3,189,935		3,189,935
Issuance of common stock and options in exchange for patents and intellectual property at $14.60 per share on November 20, 2003	10,000	146,010		146,010

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Number of shares of common stock	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
Issuance of common stock at $12.40 per share on November 21, 2003, net of share issue costs	13,152	167,305				167,305
Share options exercised on October 14, 2003	7,500	41,334				41,334
Share options exercised on May 20, 2004	5,000	27,720				27,720
Share options exercised on June 25, 2004	375	2,097				2,097
Fair value of stock options issued to directors & employees during 2004 and the expense related to options issued in prior years		418,442				418,442
Fair value of stock options issued in exchange for patents and intellectual property during 2004		31,287				31,287
Share options exercised on September 16, 2004	2,875	16,072				16,072
Issuance of common stock at $6.40 per share on December 14, 2004, net of share issue costs	1,214,719	7,192,954				7,192,954
Issuance of common stock for services rendered at $6.80 per share on April 15, 2005	4,340	29,242				29,242
Fair value of stock options issued to directors & employees and the expense related to options issued in prior years		240,928				240,928
Issuance of common stock at $5.40 per share on August 4, 2005, net of	571,429	2,931,871				2,931,871

share issue costs				
Issuance of common stock for services rendered at $5.00 per share on August 4, 2005	10,787	53,780		53,780
Issuance of common stock at $5.40 per share on September 5, 2005, net of share issue costs	206,777	1,087,496		1,087,496

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Number of shares of common stock	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
Issuance of common stock at $10.20 per share on December 20, 2005, net of share issue costs	715,000	6,886,824				6,886,824
Issuance of common stock and warrants at $10.40 per share on June 26, 2006, net of share issue costs	932,875	8,795,320				8,795,320
Issuance of common stock at $10.60 per share on June 30, 2006, net of share issue costs	9,250	97,501				97,501
Share options exercised on April 11, 2006	4,117	32,343				32,343
Fair value of stock options issued to directors & employees and the expense related to options issue in prior years		351,186				351,186
Cumulative translation adjustment (from inception to date)					666,408	666,408
Cumulative net loss (from inception to date)				(25,543,238)		(25,543,238)
Balance June 30, 2006	7,313,447	$ 41,261,692	$	$ (25,543,238)	$ 666,408	$ 16,384,862
Other comprehensive loss:						
Translation adjustment					3,658,187	3,658,187
Net loss				(20,563,357)		(20,563,357)
						(16,905,170)

Total comprehensive loss				
Issuance of common stock and warrants at $10.40 per share on July 3, 2006, net of share issue costs	980,515	9,676,197		9,676,197
Issuance of common stock and warrants at $10.40 per share on November 1, 2006, net of share issue costs	933,171	9,212,511		9,212,511
Issuance of common stock for services rendered at $11.60 per share on May 23, 2007	2,500	35,046		35,046
Share options exercised on May 28, 2007	43	603		603

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Number of shares of common stock	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
Fair value of stock options issued for services rendered during 2007		18,567				18,567
Fair value of stock options issued to directors & employees and the expense related to options issued in prior years		1,314,513				1,314,513
Balance June 30, 2007	9,229,676	$ 61,519,129	$	$ (46,106,595)	$ 4,324,595	$ 19,737,129
Other comprehensive loss:						
Translation adjustment					3,208,692	3,208,692
Net loss				(25,956,248)		(25,956,248)
Total comprehensive loss						(22,747,556)
Share options exercised on July 25, 2007	515	7,633				7,633
Share options exercised on August 8, 2007	15	217				217
Share options exercised on September 9, 2007	167	1,896				1,896
Issuance of common stock at $15.00 per share on September 11, 2007, net of share issue costs	762,722	11,082,931				11,082,931
Issuance of common stock at $16.20 per share on October 5,	348,389	5,475,757				5,475,757

2007, net of share issue costs					
Fair value of stock options issued on completion of loan facility		452,986			452,986
Fair value of stock options issued for services rendered during 2008		6,727			6,727
Fair value of stock options issued to directors & employees and the expense related to options issued in prior years		2,197,012			2,197,012
Balance June 30, 2008	10,341,484	$ 80,744,288	$ (72,062,843)	$ 7,533,287	$ 16,214,732

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

	Number of shares of common stock	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
Other comprehensive loss:						
Translation adjustment					(716,727)	(716,727)
Net loss				(43,867,658)		(43,867,658)
Total comprehensive loss						(44,584,385)
Issuance of non-vested shares on October 6, 2008	225,000					
Issuance of common stock on acquisition of Neosil, Inc. on October 16, 2008	819,378	3,831,985	2,812,200			6,644,185
Issuance of common stock and warrants at $6.05 per share on October 23, 2008, net of share issue costs	3,980,259	20,948,574				20,948,574
Share options exercised on June 15, 2009	5,000	32,869				32,869
Fair value of stock options issued for services rendered during 2009		105,661				105,661
Fair value of stock options and restricted common stock issued to directors & employees and the expense related to options issued in		2,496,197				2,496,197

prior years

Balance June 30, 2009	15,371,121	$ 108,159,574	$ 2,812,200	$ (115,930,501)	$ 6,816,560	$ 1,857,833

See accompanying notes to financial statements.

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PEPLIN, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended June 30,			For the period from inception (December 7, 1999) to June 30, 2009
	2009	2008	2007	
Operating activities:				
Net loss	$ (43,867,658)	$ (25,956,248)	$ (20,563,357)	$ (115,930,501)
Non-cash items:				
Depreciation, amortization and accretion	607,697	525,274	304,385	1,752,551
Amortization of borrowing costs	776,197	579,745		1,355,941
Loss on sale of plant and equipment	87,605	160	83,574	176,458
Stock-based compensation	2,601,858	2,203,739	1,333,080	7,650,138
Net unrealized (gain) loss on foreign exchange	3,909,382	(462,579)	750,595	3,698,724
Neosil acquisition costs	468,527			468,527
Impairment of patents				354,589
Interest paid reclassified as financing cash flow	975,075	611,091		1,586,166
Changes in operating assets and liabilities:				
Receivables and other assets	1,252	(4,086,121)	521,228	(4,035,769)
Prepaid expenses	14,439	(34,398)	(960,752)	(1,019,233)
Lease deposits	(457,316)	(17,821)	(162,193)	(638,357)
Payables and other accruals	6,254,534	182,289	1,058,882	9,830,896
Accrued employee benefits	272,363	188,289	105,463	624,220
Deferred license fee income				(467,185)
Other				115,950
Net cash used in operating activities	(28,356,045)	(26,266,580)	(17,529,095)	(94,476,885)
Investing activities:				
Proceeds from sale of plant and equipment	889	8,543	144	41,328
Purchase of plant and equipment	(898,132)	(845,742)	(685,930)	(4,154,373)
Cash received on acquisition of Neosil	4,389,740			4,389,740
Payments for short term investments				(2,988,967)
Proceeds from short term investments				2,988,967
Proceeds on maturity of available-for-sale securities	2,220,989			2,220,989
Payments for intangible assets				(205,321)
Net cash provided by/(used in) investing activities	5,713,486	(837,199)	(685,786)	2,292,363

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended June 30,			For the period from inception (December 7, 1999) to June 30,
	2009	2008	2007	2009
Financing activities:				
Proceeds from share issues	24,067,380	17,051,445	20,344,088	104,458,294
Proceeds from exercise of options	32,869	9,746	603	209,685
Share issue costs		(547,764)	(1,402,396)	(4,774,188)
Restricted cash		(34,376)	(173,825)	(318,462)
Payments for shares repurchased				(1,199,484)
Proceeds from cancellation of shares due to reorganization		77,895		77,895
Payment for cancellation of shares due to reorganization	(20,362)	(57,533)		(77,895)
Proceeds from borrowings		15,000,000		15,193,968
Borrowing costs paid	(999,273)	(1,575,734)		(2,575,006)
Repayment on borrowings	(5,148,551)	(1,164,632)		(6,582,401)
Net cash provided by financing activities	17,932,063	28,759,047	18,768,470	104,412,406
Effect of exchange rate on cash and cash equivalents	(2,768,948)	3,329,305	2,852,377	5,523,202
Net increase (decrease) in cash and cash equivalents	(7,479,444)	4,984,573	3,405,966	17,751,089
Cash and cash equivalents at beginning of year	25,230,533	20,245,960	16,839,994	
Cash and cash equivalents at end of year	$ 17,751,089	$ 25,230,533	$ 20,245,960	$ 17,751,089
Supplemental non-cash activities:				
Issue of shares in exchange for the net assets of the Peplin Unit Trust	$	$	$	$ 314,644
Issuance of shares in exchange for the assets of Neosil, Inc.	6,644,185			6,644,185
Acquisition of plant and equipment by means of capital leases				60,964
Issuance of options on completion of loan facility				452,986
Issuances of common stock and options for services	105,661	6,727	54,234	

Acquisition of patents and intellectual property by way of issuance of common stock and options			146,010
Supplemental cash activities:			
Income tax paid	1,734	20,586	22,320

See accompanying notes to financial statements.

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Note 1: Summary of significant accounting policies

Organization and nature of operations

Peplin, Inc. (Peplin or the Company) is a development stage specialty pharmaceutical company focused on advancing and commercializing innovative medical dermatology products. The Company is currently developing PEP005 (ingenol mebutate) Gel, or PEP005 Gel, which is the first in a new class of compounds that are naturally occurring and have the potential to treat cancers and pre-cancerous skin lesions. The Company s lead product candidate, which is in Phase III clinical trials, is a patient-applied topical gel containing PEP005, a compound the use of which the Company has patented for the treatment of actinic keratosis, or AK. The Company s other product candidate is a physician-applied topical gel for the treatment of superficial basal cell carcinoma, or superficial BCC, PEP005 Gel for BCC. The active compound in each product is a small molecule extracted and purified from the sap of euphorbia peplus, a rapidly growing, readily available plant.

Peplin was formed for the purpose of reorganizing its corporate structure. On October 16, 2007, Peplin acquired all the outstanding ordinary shares of Peplin Limited pursuant to a Scheme of Arrangement. This transaction is referred to as the Reorganization. Prior to the closing of the Reorganization, Peplin had no business or operations and following the closing of the Reorganization, Peplin s business and operations consisted solely of the business and operations of Peplin Limited and Peplin s other subsidiaries.

Peplin is currently listed on the Australian Securities Exchange (ASX), where its common stock and options trade in the form of Chess Depository Interests (CDIs).

Basis of presentation

The Company s principal activities to date have included technology development, obtaining research and funding grants, securing patents and intellectual property rights and securing finance for working capital and capital expenditures. Accordingly, these financial statements are presented as those of a development stage enterprise, as prescribed by Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

Liquidity and capital resources

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has incurred significant losses and negative cash flows from operations since its inception. At June 30, 2009, the Company had an accumulated deficit of $115.9 million. In connection with the potential acquisition of the Company by LEO Pharma A/S (LEO) (described in Note 17 *Subsequent Events* below), the Company and LEO have entered into a Loan Agreement, dated as of September 2, 2009, pursuant to which LEO has agreed to provide loans to Peplin of up to an aggregate principal amount of $24,000,000 (the Loan Agreement), which, together with cash and cash equivalents at June 30, 2009, will be sufficient to fund continuing operations for 12 months. Peplin can request no more than one advance on the Loan Agreement (Advances) in any 15-day period, and each advance cannot exceed the lesser of (a) $2,000,000 and (b) the amount of Peplin s budgeted cash expenditures and transaction expenses for the month, but in no event shall the aggregate principal amount of all outstanding Advances exceed the aggregate amount available under the Loan Agreement. The principal of, and accrued interest on, the Advances must be repaid on that date which is the earlier to occur of: (1) April 1, 2011; (2) the date that is seven days after the effective date of the Merger; (3) the date that is seven days after the consummation of an acquisition by Peplin by a third party other than LEO; and (4) the date that is six months after the termination of the $15 million, three-year loan facility (the Loan Facility) with General Electric Capital Corporation (GE) and Oxford Finance Corporation (Oxford and together with GE, the Lenders).

In the event that the merger agreement with LEO is terminated, the Company will be unable to draw down further funds under the Loan Agreement and will need to raise additional funds to continue operations, service the Loan Facility and repay Advances made to LEO under the Loan Agreement. In addition, under certain circumstances the Company would need to pay LEO a $10 million break-up fee. The Company

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cannot give assurances that the funding, if needed, will be available on terms attractive to it, or at all. If the Company is unable to raise additional capital to fund its operations, it will need to curtail planned activities to reduce costs and the Company may not be able to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company s ability to continue as a going concern.

Translation of foreign currencies

Effective October 1, 2008 the functional currency of the Company changed from Australian dollars to U.S. dollars. The change was made prospectively, in accordance with SFAS No. 52, *Foreign Currency Translation,* and was determined based on the significant changes in economic facts and circumstances of the parent entity that occurred in October 2008.

Principles of consolidation

The financial statements include the accounts of Peplin, Inc. and its wholly-owned subsidiaries, Peplin Limited, Peplin Unit Trust, Peplin Research Pty Ltd, Peplin Operations Pty Ltd, Peplin Biolipids Pty Ltd, Peplin Operations USA, Inc., Neosil, Inc. and Peplin Ireland Limited. All intercompany balances and transactions have been eliminated on consolidation.

Cash and cash equivalents

Cash and cash equivalents, comprise cash held in a variety of interest-bearing instruments, including term deposits with high credit rated Australian banks, with a maturity from purchase date of three months or less. For the purposes of the statement of cash flows, cash includes cash and cash equivalents, as defined above.

Restricted cash

Non-current restricted cash represents deposits held with financial institutions as security for the Company s business credit card facilities, and security deposits with the bank issued under the terms of the lease of the Company s Newstead, Brisbane office.

Deferred costs

Deferred costs primarily represent accounting, legal costs and other direct costs incurred that are directly attributable to capital raising activities. Deferred costs are offset against funds raised once a capital raising is complete.

Plant and equipment

Plant and equipment are stated at cost, net of accumulated amortization and depreciation. Plant and equipment are depreciated on a straight-line basis over the shorter of estimated useful life of the assets or the lease term.

Classes of plant and equipment and related useful lives are as follows:

Asset	*Estimated useful life (Years)*
Plant and equipment	2-10
Leasehold improvements	5-10
Office equipment	2-10
Computer software	2-3

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Impairment of long lived assets

Pursuant to guidance established in SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets,* the Company evaluates if long lived assets are impaired whenever indicators of impairment are present. Management considers assets to be impaired if the carrying value exceeds the future projected cash flows from related operations (undiscounted and without interest charges). If impairment is deemed to exist, the assets will be written down to fair value with the fair value determined based on an estimate of discounted future cash flows. Management also re-evaluates the periods of depreciation or amortization to determine whether subsequent events and circumstances warrant revised estimates of useful lives.

Revenue recognition license fees

The Company applies the revenue recognition criteria outlined in Securities Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and Emerging Issue Task Forces (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. In applying these revenue recognition criteria, the Company considers a variety of factors in determining the appropriate method of revenue recognition under its revenue arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

The Company s license fee revenues consist of amounts received under a license and collaboration agreement with Allergan Inc. (Allergan) entered into in November 2002. License fee revenues include a non-refundable upfront payment, quarterly installment payments and subsequent milestone payments based on performance. Upon receipt, all such payments, including the milestone payments which the Company deems to be inseparable from the overall license fee, are recorded as deferred license fee income and are recognized as revenue ratably over the term of the license. The license and collaboration agreement also provides for certain cost sharing of research and development activities performed by Peplin for which Allergan reimbursed Peplin $234,505 during the 2005 financial year which is reflected in research and development expense in the accompanying statement of operation. This agreement was cancelled in October 2004 and Allergan paid a cancellation fee of $1,332,076 which was recognized as license fee revenue. Pursuant to a termination agreement, Allergan may receive certain future royalties from Peplin (refer to Note 9 for further details). Additionally, all amounts that had been recorded as deferred license fee income at the date of cancellation were recognized as license fee revenue at that time.

Government grant income

Government grants, which support the Company s research efforts in specific projects, generally provide for reimbursement of approved costs incurred. Grant receipts are recognized as income when research and development expenditure to which the particular grant relates to have been incurred.

The Company has received two grants under the Australian Government s R&D START program, as described in Note 9(d), where the grant payments were made quarterly in advance based on estimated expenditures. In these instances, the advance payments received are classified as deferred income until the qualified expenditures have been incurred. The final START grant was completed in August 2004.

In 2006, the Company was awarded a research grant under the Australian Government s Pharmaceuticals Partnerships Program (the P3 Program). Under the terms of the P3 Program, the Company receives grant proceeds in arrears. Where qualifying expenses have been incurred and grant proceeds not yet received, a receivable for grant income is recorded in the balance sheet. The total amount recognized under the P3 Program for the years ended June 30, 2007, 2008 and 2009 was $179,752, $1,369,013 and $586,660, respectively. This grant was completed at June 30, 2009, therefore apart from the current grant income receivable for expenditure incurred to June 30, 2009, the Company is no longer entitled to funding under this grant. There are no unfulfilled conditions or contingencies attaching to this grant nor are there any repayment provisions.

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Interest income

Interest income is recognized as it accrues.

Research and development expenditure

Research and development expenditure costs are charged as an expense when incurred. Such costs include direct salaries, stock options expense, patient recruitment fees, contract research costs, laboratory expenses, patent costs and certain related administrative expenses.

Patents

Costs associated with filing, maintaining, defending and protecting patents for which no future benefit is reasonable assured are expensed as incurred.

Stock-based compensation

The Company accounts for stock-based employee compensation arrangements using the fair value based method as prescribed in accordance with the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123R, *Accounting for Stock Based Compensation (revised 2004)* (SFAS 123R). The Company has applied the measurement and valuation provisions of SFAS 123R for all stock options granted since the Company s inception. Stock based compensation costs for employees is measured at the grant date, based on the fair value of the award and is recognized as an expense over the period awards are expected to vest. Under the provisions of SFAS 123R, employee stock compensation is estimated using the Black-Scholes option-pricing model. The Black-Scholes option pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are the estimates of the expected term of the award and the expected volatility of the market price of the Company s stock. In accordance with SAB 110, *Amending and Replacing a Portion of the Staffs Views About Valuing Share-based Payments to Continue Acceptance, Under Certain Circumstances, of the Simplified Method* (SAB 110) the Company uses the simplified method to develop an estimate of the expected term of its awards.

For those options issued prior to June 30, 2006, the Company has utilized an average volatility based on ASX listed guideline companies within the biotechnology sector as there was insufficient company trading history in order to determine an accurate volatility rate. For options issued subsequent to June 30, 2006 through to the date of the Reorganization, the Company calculated expected volatility based on the Company s own trading activity data. Upon the Reorganization, primarily due to the underlying security changing from an Australian ordinary share to U.S. common stock, volatilities are based on NASDAQ-listed peer companies within the biotechnology sector. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on historical experience. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results differ from the Company s estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised.

Options granted to consultants and other non-employees are accounted for in accordance with EITF consensus No. 96-18, *Accounting for Equity Instruments that are issued to Other than Employees for Acquiring, or in Connection with Selling Goods or Services*. Compensation costs for stock options granted to non-employees are measured at the earlier of the date at which the commitment for performance to earn the equity instrument or the date at which the counterparty s performance is complete. The fair value of stock options, as calculated using a Black-Scholes option valuation model, are expensed over the performance period and are subject to remeasurement over their vesting terms.

Net loss per share

Basic and diluted net loss per share has been calculated by dividing net loss by the weighted average common stock outstanding during the periods. There are 3,793,976 stock options, non-vested shares and

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warrants that have not been included in the computation of net loss per share in the periods presented as their effect is anti-dilutive. For additional disclosures regarding stock options see Note 12.

Foreign currency transactions

Foreign currency transactions are initially remeasured to the Company s or its subsidiaries respective functional currency. At the balance sheet date amounts payable and receivable in foreign currencies are remeasured to the functional currency at rates of exchange current at that date. Resulting exchange losses of $986,493, $370,243, $4,230,667 and $5,661,535 for the years ended June 30, 2007, 2008, 2009 and the period from inception to June 30, 2009 respectively, are included in earnings.

Use of estimates

The preparation of financial statements in conformity with 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 financial statements and the reported results of operations during the reporting period. Actual results could differ from those estimates. Accounting estimates have been applied to calculate accruals for employee entitlements, asset retirement obligations, impairment of assets and expenses for stock-based compensation.

Financial instruments

Financial instruments consists principally of cash and cash equivalents, grant income receivable, accounts payable and notes payable. As of June 30, 2009, the fair values of financial instruments, including cash and cash equivalents, grant income receivable and accounts payable, approximate their carrying value due to their short term nature. The Company s notes payable were initially recognized at the value of the cash proceeds received. The fair value of notes payable is calculated by discounting the expected future cash flows at the prevailing market interest rate.

Accruals for employee entitlements

The Company accrues compensated absences and related benefits as current charges to earnings when the following criteria are met: (i) the employee s right to receive compensation for the future absences is attributable to services already performed by the employee; (ii) the employee s right to receive the compensation for the future absences is vested, or accumulates; (iii) it is probable that the compensation will be paid; and (iv) the amount of compensation is reasonably estimable.

Asset retirement obligations

The Company accounts for its contractual obligation to restore certain of its leased facilities under the provisions of SFAS No. 143, *Accounting for Asset Retirement Obligations* (SFAS 143). SFAS 143 requires legal obligations associated with the retirement of long-lived assets to be recognized at their fair value at the time the obligations are incurred. Upon initial recognition of a liability, the costs are capitalized as part of the related long-lived asset and allocated to expense over the useful life of the asset. Changes in asset retirement estimates are capitalized as part of the long-lived asset and expensed prospectively over the useful life of the asset. The discount rate used when estimating the fair value of the asset retirement obligation is a credit-adjusted risk-free interest rate with the same expected maturity as the retirement obligation.

Notes payable

Notes payable are initially recognized at the value of the cash proceeds received. After initial recognition, notes payable are subsequently measured at amortized cost using the effective interest method. Fees paid on the establishment of the loan facilities (Debt issuance costs) are capitalized as an asset and amortized over the life of the loan. Debt issuance costs payable at the completion of the facility are included as a non-current liability in the accompanying consolidated balance sheets.

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Income taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). SFAS 109 requires recognition of deferred tax assets and liabilities for the estimated future tax consequences of events attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases as well as operating loss and tax credit carry forwards. 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 are expected to be recovered or settled. The effect of deferred tax assets and liabilities of a change in tax rates is recognized in the statement of operations in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48) on July 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

Leased assets

All of the Company s leases for the years ended June 30, 2007, 2008 and 2009 are considered operating leases. Some lease agreements contain rent escalation clauses based on the consumer price index. For purposes of recognizing incentives and minimum rental expenses on a straight-line basis over the original terms of the leases, the Company uses the date of initial possession to begin amortization, which is generally when the Company enters the space. The Company does not assume renewals in its determination of the lease term unless the renewals are deemed by management to be reasonably assured at lease inception. The costs of operating leases are charged to the consolidated statement of operations on a straight line basis over the lease term.

Recent accounting policies

Effective July 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157), on a prospective basis for financial assets and liabilities, which requires that the Company determine the fair value of financial assets and liabilities using the fair value hierarchy established in SFAS 157. In February 2008, the FASB issued FASB Staff Position No. FAS 152-7, *Effective Date of FASB Statement no. 157,* which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. The adoption of SFAS 157 did not have a material impact on the Company s results of operations and financial condition as of and for the year ended June 30, 2009. See Note 14 for information and related disclosures regarding the Company s fair value measurements.

In June 2009, the FASB issued Statement No. 165 *Subsequent Events* (Statement 165). Statement 165 requires companies to disclose the period over which subsequent events have been evaluated while also requiring a distinction between recognized and non-recognized subsequent events. Statement 165 is effective for interim or annual financial periods ending after 15 June 2009. The Company determined that Statement 165 did not have a material impact on the Company s consolidated financial statements.

Note 2: Concentrations of credit risk, other risks and uncertainties

Cash and cash equivalents consist of financial instruments that potentially subject the Company to concentration of credit risk to the extent of the amount recorded on the balance sheet. The Company s cash and cash equivalents are primarily deposited with Commonwealth Bank of Australia (CBA), Bank of Western Australia (which was acquired by CBA in December 2008 and was a wholly-owned subsidiary of CBA at June 30, 2009) and Wells Fargo & Company. The Australian Government recently announced that it would guarantee funds currently held with Australian banks. The Guarantee is free for funds up to A$1

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million, and an insurance premium can be paid by way of an interest rate reduction to guarantee amounts above this amount. The Company has paid the insurance premium to cover its deposits above A$1 million with Bank of Western Australia only. The Company is exposed to credit risk in the event of default by the banks holding the cash and cash equivalents (and the Australian Government) to the extent of the amount recorded on the balance sheets. The Company is also exposed to interest rate risk to the extent of the amount recorded on the balance sheets.

In 2008, the Company completed the Loan Facility. The Company s exposure to interest rate risk on the Loan Facility is the difference between the market interest rate and the fixed interest rate on this loan of 8.50%.

The Company relies on a single third party supplier for the formulation and filling of its late stage product candidates.

Note 3: Other assets

	June 30,	
	2009	**2008**
Current assets		
Borrowing costs (refer to Note 8)	$ 436,423	$ 938,535
Lease incentive receivable	324,835	
Other	101,841	43,865
	$ 863,099	$ 982,400
Non-current assets		
Borrowing costs (refer to Note 8)	$ 63,072	$ 629,206

Note 4: Plant and equipment

	June 30,	
	2009	**2008**
Plant and equipment	$ 1,722,456	$ 1,743,658
Leasehold improvements	1,559,064	1,350,672
Office equipment (including computer software)	954,851	894,721
Plant and equipment, at cost	4,236,371	3,989,051
Accumulated depreciation	(1,553,294)	(1,164,940)
Plant and equipment, net	$ 2,683,077	$ 2,824,111

Depreciation expense related to plant and equipment amount to $304,385, $525,274, and $601,580 for the years ended June 30, 2007, 2008 and 2009.

Note 5: Income taxes

The provision for income taxes consists of:

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	Years ended June 30,		
	2009	**2008**	**2007**
Current			
US Federal			
US State	$ 1,734	$ 20,586	$
Foreign			
Total	1,734	20,586	
Deferred			
US Federal			
US State			
Foreign			
Total			
Provision for taxes	$ 1,734	$ 20,586	$

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the corresponding amount used for income tax purposes. Significant components of the Company s deferred tax items, which are predominantly long term in nature, are as follows:

Deferred income tax

	June 30,	
	2009	**2008**
Deferred tax liabilities		
Foreign currency balances	$	$ (181,452)
Depreciation	(107,427)	(194,334)
Deferred transaction costs		(290,740)
Accrued income	(66,717)	(90,366)
Gross deferred tax liabilities	(174,144)	(756,892)
Deferred tax assets		
Borrowing costs	179,379	$ 77,723
Reorganization costs	184,679	292,124
Sundry creditors and accruals	5,011	74,617
Employee benefits	361,414	268,830
Patent costs	561,053	596,594
Tax effect of intercompany transaction	11,562,450	13,717,050
Doubtful debts	4,561	5,411
Asset retirement obligation	7,537	4,306
Stock options	539,331	6,728

Foreign currency balances	187,422	
Share issue transaction costs	367,995	736,091
Losses available for offset against future taxable income	6,901,680	8,249,798
Deferred R&D costs	3,942,331	2,123,022
Gross deferred tax assets	26,745,810	26,152,294
Valuation allowance	24,630,699	(25,395,402)
Deferred tax assets	174,144	756,892
Net deferred tax assets	$	$
The valuation allowance consists of:		
US	$ 2,049,484	$ 2,510,377
Foreign	22,581,215	22,885,025
	$ 24,630,699	$ 25,395,402

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At June 30, 2009 the Company had gross operating tax loss carry forwards of approximately $26,950,975 (June 30, 2007: $19,278,609 and June 30, 2008: $31,140,389), which may be adjusted if the Company is unable to comply with the recognition criteria for carry forward tax losses under Australian, US or Irish taxation laws. The Company is continuously assessing compliance with the relevant recognition rules as tax laws change and business transactions occur. $18,727,387 of the Company s net operating tax loss carry forwards as of June 30, 2009 are attributable to 2002-2009 tax losses generated within the Company s Australian tax consolidated group, and can be carried forward indefinitely. Pursuant to Australian tax law, tax losses may not be available and would thus be derecognized where there has been a greater than 50% change in the cumulative ownership of the Company combined with a change in the Company s business or capital structure. Presently, there is no knowledge of the Company s 2002-2009 tax losses being at risk of derecognition based on past cumulative changes in ownership. As a result of these tax loss carry forwards, the Company has significant deferred tax assets, however due to the Company s lack of earnings history, realization of these deferred tax assets is not more likely than not, therefore the deferred tax assets have been fully offset by a valuation allowance.

The remaining Peplin losses of approximately $8,223,588 are US losses which have a carry forward period to between calendar years 2027-2029. In addition, the Company acquired Neosil, Inc. (Neosil), a privately held, dermatology-focused company, in an all stock transaction. As of June 30, 2009, Neosil had federal net operating carry forward losses of approximately $26 million, however the Company has determined that uncertainty exists around the ability to utilize the Neosil tax losses in future periods (refer to the FIN 48 discussion and analysis below).

Future events such as capital injections and changes in the Company s business or capital structure require evaluation as to the impact on continued availability of historical tax losses to offset future income. Federal and state laws impose substantial restrictions on the utilization of net operating loss and tax credit carryforwards in the event of an ownership change as defined in Section 382 of the Internal Revenue Code. The Company has not yet determined whether an ownership change occurred due to stock transactions in each of the reporting years disclosed. If an ownership change occurs, utilization of the net operating loss and tax credit carryforwards could be significantly reduced.

Currently, the income taxes balance sheet account consists of $34,774 for US federal tax receivable, classified under other current assets in the balance sheet as at June 30, 2009. This represents income tax paid in respect of the June 30, 2007 income tax return which is expected to be recouped from losses incurred in the 2008 year. This had no effect on the statement of operations for the year ended June 30, 2009, and is expected to be received in early 2010. The income tax expense for the year ended June 30, 2009 represents the minimum US state income tax amount payable.

On June 28, 2007, Peplin Ireland Limited was incorporated in Ireland as a wholly-owned subsidiary of Peplin Limited, in order to take advantage of European expertise in intellectual property development. On June 29, 2007 Peplin Ireland Limited entered into an agreement for an upfront payment of $40.3 million with Peplin Research Pty Ltd as trustee for the Peplin Unit Trust to license intellectual property (IP) relating to Euphorbia peplus and PEP005 Gel on an exclusive worldwide basis. The license agreement is between consolidated entities and the intercompany sale payable and receivable are eliminated. However, since the entities are in different tax jurisdictions a taxable gain is created for the consolidated Australian tax group which is recognized as a gain on the sale of the license agreement of IP. The tax loss carry forward within the group offset the taxable gain. With respect to an intercompany sale of property among members of a consolidated financial group, FAS 109 prohibits recognition of a deferred tax asset for the difference between the tax basis of the assets sold in the buyer s tax jurisdiction and their cost as reported in the consolidated financial statements. Therefore the tax benefit of any future Irish tax deductions attributable to the purchase of the IP is not recognized as a deferred tax asset. To account for the utilization of the Australian carryforward losses, the deferred tax asset attributable to the carryforward losses was reduced by the amount of the gain recognized, and the valuation allowance against the deferred tax asset was correspondingly reduced. As Peplin Ireland Limited is currently in a pre-commercialization period, it is unable to claim expenses for taxation purposes. Therefore no amortization of the IP has been expensed in this period, and no tax losses are carried forward at June 30,

2009. As the company is currently in a pre-commercialization period, a deferred tax asset of $3,942,331 of deferred R&D costs has been recognized

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on the basis that these costs have been incurred within three years of commercialization, however a full valuation offsets this amount.

Reconciliation of income tax expense attributable to continuing operations and income tax expense resulting from applying the statutory tax rate to pre-tax income from continuing operations:

	Years ended June 30,		
	2009	**2008**	**2007**
Tax at the applicable rates [1]	$ (14,915,004)	$ (8,825,124)	$ (6,169,007)
State income taxes, net of U.S. federal tax benefit	(843,110)	(415,153)	
Jurisdiction tax rate adjustment	1,197,009	375,579	
Prior year true up:			
R&D concession	240,816	558,624	(213,697)
Other	27,271	147,094	
Permanent differences:			
Non-deductible items	943,890	831,666	405,321
Tax effect of eliminated intercompany transactions	6,740,329	3,307,196	10,380,995
Provision for uncertainty of realization of tax assets			(11,293,481)
Derecognition of uncertain tax losses	3,872,763	1,395,466	
Derecognition of Patents not relating to know-how		277,739	
R&D concessions		(256,871)	(443,200)
Other deductible amounts	(4,886)		
Non-assessable items		(483,306)	
Net taxable loss	(2,740,922)	(3,087,090)	(7,333,069)
Valuation allowance	2,742,656	3,107,676	7,333,069
Tax expense	$ 1,734	$ 20,586	$

[1] Prior to June 30, 2008 the statutory tax rate was based on the Australian rate of 30%. As of October 16, 2007 the Company became a US domestic company, therefore the June 30, 2008 and June 30, 2009 rate is the US federal rate

of 34%.

The Company s deferred income tax balance and the difference between income tax computed at the US federal statutory rate and income tax expense is primarily the result of tax losses carried forward. The pre-tax losses for the Australian tax consolidated group and Peplin Ireland Limited are $818,381 and $104,750 respectively, as of June 30, 2009 ($0 at June 30, 2007, and $14,871,173 and $43,319 at June 30, 2008).

The change in the valuation allowance and the corresponding change in the deferred tax asset for the years ended June 30, 2007, 2008 and 2009 are as follows:

		Additions		
Description	**Balance at Beginning of Period**	**Charged to Costs and Expenses**	**Charged to Other Accounts (1)**	**Balance at End of Period**
Year ended June 30, 2007				
Deferred income tax valuation allowance	$ 9,497,202	7,333,069	2,400,300	$ 19,230,571
Year ended June 30, 2008				
Deferred income tax valuation allowance	$ 19,230,571	3,107,676	3,057,155	$ 25,395,402
Year ended June 30, 2009				
Deferred income tax valuation allowance	$ 25,395,402	2,742,656	(3,507,359)	$ 24,630,699

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(1) Recognized through the balance sheet/(equity) as a result of share issue costs, net of foreign exchange. Includes currency translation adjustment recognized as a component of other comprehensive income.

In 2008, we established a FIN 48 unrecognized tax benefit relating to pre-2002 consolidated tax losses in Australia, where sustainability of the losses is not considered to be more likely than not. Due to Australian tax legislation enacted in 2002 (if the losses meet recognition criteria), these losses could be limited to offset a portion (currently estimated to be 10.2% subject to further reduction for future capital injections, into the Australian tax consolidated group) of future taxable income on an annual basis, and therefore do not meet the more likely than not threshold for recognition of sustainability under audit by the appropriate taxing authorities.

In 2009, we have established a FIN 48 unrecognized tax benefit relating to 2008 deferred R&D costs in Ireland of $1.9 million, where sustainability of the losses is not considered to be more likely than not. Pre-commercialization losses are only deductible if they are incurred within three years prior to commercialization. As the Company does not believe that the commercialization will occur before June 30, 2010, deductibility of these losses is not considered more likely than not to be sustained under audit by the relevant tax authority.

On October 16, 2008, the Company acquired Neosil, Inc. As of the date of acquisition, Neosil had tax effected carried forward losses of $10,611,535 and research and development credits of $1,327,213 Due to Neosil s history of ownership changes and uncertainty as to the availability to use it s losses it is not considered more likely than not that the losses would be sustained under audit by the relevant tax authorities and the Company has established a FIN 48 unrecognized tax benefit against all of the Neosil tax attributes.

In 2009, the Company established a FIN 48 unrecognized tax benefit of $1.9 million relating to carry forward tax losses in the U.S. that are subject to continuity of ownership annual limitations, where sustainability of the losses is not considered more likely than not. This conclusion was reached after the Company s management performed a change of ownership analysis on June 30, 2009.

Our policy is to include interest and penalties related to gross unrecognized tax benefits within our provision for income taxes. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced in the period that such determination is made, and reflected as a reduction of the overall income tax provision, to the extent that the interest expense had been provided through the tax provision.

Total amount of unrecognized tax benefits:

Balance at July 1, 2007	$ 1,395,466
Increase in balance due to current year tax positions	
Balance at June 30, 2008	$ 3,872,763

Increase in balance due to current year tax positions	1,931,796
Increase in balance on acquisition of Neosil	11,938,748
Balance at June 30, 2009	$17,206,977

The tax years remaining open to tax examination by the taxing authorities for companies within Peplin, Inc. are 2000-2009 for the Australian consolidated group, 2006-2009 for the U.S. entities, and 2006-2009 for Peplin Ireland Limited.

Note 6: Related party disclosures

Pursuant to a purchase agreement for shares and options (under the Entitlement and International Offers) entered into in May 2006, by and among Peplin and MPM BioVentures IV-QP L.P., MPM BioVentures IV, L.P. and MPM Asset Management Investors BV4, or collectively, MPM, Peplin undertook to procure that a resolution be put to shareholders to appoint Mr. Scopa, who is a managing director

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of MPM, as a director and also to appoint a person nominated by MPM as a director. Mr. Scopa was elected as a director by shareholders in June 2006 and Dr. Bauer, MPM s nominated person, was elected by shareholders in October 2006. Following each respective election, Mr. Scopa and Dr. Bauer have served as directors under the terms of the constitution of Peplin and no further obligations in relation to their appointments exist under the purchase agreement. The Company paid MPM fees related to the Entitlement and International Offers in the amount of $57,240 during the year ended June 30, 2007.

On October 5, 2007, the Company completed a private placement of shares pursuant to subscription agreements. As a result 348,389 shares were issued to entities affiliated with MPM BioVentures IV LLC. The shares were issued at $16.20 (A$18.00) per share. In addition, Peplin Limited reimbursed MPM BioVentures IV LLC $14,700 of its legal costs incurred in connection with the transaction.

On June 12, 2008, the Company entered into a contract with Dr. Gary Patou to act as Chief Medical Officer. As part of the contract Dr. Patou was granted an option to purchase 10,000 shares of the Company s common stock, with an exercise price of $7.37 per share, vesting in twelve equal monthly installments with the first monthly installment vesting on June 12, 2008. Dr. Patou is a Managing Director of MPM Asset Management LLC. Dr. Patou has no ownership interest, or voting or investment power with respect to the shares of common stock held by funds affiliated with MPM BioVentures IV LLC, a holder of more than 5% of the Company s outstanding common stock. The options expire on June 11, 2018.

On October 23, 2008, the Company completed a private placement pursuant to subscription agreements. As a result 1,157,655 shares and 385,885 warrants to acquire shares were issued to entities affiliated with MPM BioVentures IV LLC. The shares were issued at $6.05 per share. The warrants have an exercise price of $7.86 and expire on October 22, 2012. In addition, Peplin reimbursed MPM BioVentures IV LLC $22,500 of its legal costs incurred in connection with the transaction.

On February 1, 2009, the Company entered into a joint contract with Robert Millman and MPM to provide intellectual property consulting services. As part of the contract Mr. Millman was granted an option to purchase 10,000 shares of the Company s common stock, with an exercise price of $8.03 per share, vesting in twelve equal monthly installments with the first monthly installment vesting on March 9, 2009. Mr. Millman is a Managing Director of MPM Asset Management LLC. Mr. Millman has no ownership interest, or voting or investment power with respect to the shares of common stock held by funds affiliated with MPM BioVentures IV LLC, a holder of more than 5% of the Company s outstanding common stock. The options expire on February 8, 2019.

On February 9, 2009, Dr. Patou was granted an option to purchase 10,000 shares of the Company s common stock, with an exercise price of $8.03 per share, vesting in twelve equal monthly installments with the first monthly installment vesting on March 9, 2009. The options expire on February 8, 2019.

During the year ended June 30, 2009, the Company incurred costs from MPM Capital of $116,559. These costs relate to directors fees and travel costs for Jim Scopa as a member of the board, as well consulting services provided by Dr. Patou and Mr. Millman. Of the above costs incurred, approximately $5,629 of costs remains outstanding at June 30, 2009.

During the year ended June 30, 2009 the Company also incurred costs of $31,522 from GBS BioVentures, a holder of more than 5% of the Company s outstanding common stock. These costs primarily relate to directors fees for Joshua Funder, who is an employee of GBS Venture Partners Limited and a unit holder of GBS BioVentures IV, and remain outstanding at June 30, 2009.

Note 7: Asset retirement obligation

In accordance with the lease agreement terms, the Company must restore both of its leased premises situated at Newstead, Brisbane as well as its premises at Southport, Gold Coast to their original condition at the end of the lease term.

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During 2006, the Company recorded an initial asset retirement obligation in respect of the Southport premises of $58,448 and capitalized the same amount by increasing the carrying cost of the related asset. In March 2007, the lease agreement for the facility was renegotiated, resulting in an increase in the term of the lease over which the obligation is unwound. Accretion expense for the year ended June 30, 2009 of $5,614 (year ended June 30, 2007, $(10,094), and year ended June 30, 2008, $6,080) is recorded in research and development within the statements of operations. Because of the long-term nature of the liability, the greatest uncertainty in estimating the provision is the costs that will ultimately be incurred. The obligation has been calculated using a discount rate of 9.6%.

In 2009, the Company recorded an initial asset retirement obligation in respect of the new premises at Newstead of $30,128 (A$41,419) and capitalized the same amount by increasing the carrying costs of the related asset. Accretion expense for the year ended June 30, 2009 of $503 is recorded in sales, general and administration costs. Due to similar uncertainties in estimating the costs that will ultimately be incurred, the obligation has been calculated using a discount rate of 9.4%

	June 30,	
	2009	**2008**
Asset retirement obligations		
Balance at July 1	$ 74,504	$ 59,963
Liabilities incurred during the period	30,128	
Accretion expense	6,117	6,080
Effect of foreign exchange translation	(7,803)	8,461
Balance at June 30	$ 102,946	$ 74,504

Note 8: Notes payable

	June 30,	
	2009	**2008**
Current portion	$ 5,629,087	$ 5,163,171
Non-current portion	$ 2,998,467	$ 8,612,934

On December 28, 2007 the Company entered into a loan agreement with the Lenders under which Peplin Limited borrowed $15,000,000. In connection with this agreement, the Company has incurred costs related to the transaction totaling $2,031,241, including amongst other costs, a completion fee payable when the final payment is made, as well as a grant of warrants for purchase of the Company s common stock on finalization and drawdown of the facility. The completion fee is equal to 4% of the total amounts borrowed under the credit facility. The number of warrants issued was 58,987 with an exercise price of $15.26, such that the total value is the equivalent of approximately 6% of the loan amount drawn down. The exercise price was calculated using the weighted average closing share price for the 10 days prior to grant date. The fair value of the warrants was $452,986. The warrants vested immediately and have a five year term, expiring on December 27, 2012.

Beginning January 1, 2008, the Company was required to make monthly interest payments, in arrears, on the outstanding principal of the loan at a fixed rate of 8.5% per annum. Monthly repayments of principal began on May 1, 2008. All amounts outstanding under the loan agreement are due in full by December 28, 2010. The loan is collateralized by substantially all of the Company s assets other than, subject to certain limited exceptions, intellectual property. The Company can voluntarily prepay the loan in full, but not in part.

Borrowings are subject to certain financial covenants and restrictions on the ability of the Company and its subsidiaries (as guarantors) to pledge their intellectual property as collateral to a third party or

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permit a third party to restrict its ability to pledge its intellectual property. Peplin (as guarantor) has pledged 100% of the shares of the outstanding capital stock, of any class, of each of Peplin s subsidiaries. As of June 30, 2009, the Company and its subsidiaries were in compliance with all covenants. The carrying amount on the Company s balance sheet of assets that serve as collateral for borrowings totaled $23,363,507 at June 30, 2009.

Included in current and non-current other assets at June 30, 2009 are $499,495 related to costs incurred in connection with this loan agreement. These costs are being amortized to interest expense over the term of the loan agreement and such amortization totaled approximately $776,197 for the year ended June 30, 2009 (year ended June 30, 2007: $579,745, and June 30, 2006: $0).

Future maturities of long-term debt are as follows as of June 30, 2009:

Within one year	$ 5,629,087
More than one year but less than two years	2,998,467
Total	$ 8,627,554

Note 9: Commitments and contingencies

(a) Research and development expenditure

The Company has entered into a number of contracts with third parties to conduct clinical trials and research. The Company pays for these services as incurred. The Company had non-cancellable research and development commitments as follows at June 30, 2009:

2010	$ 9,078,402
2011	$ 46,909
Total	$ 9,125,312

These costs are included in research and development expense as incurred.

(b) Sales, general and administrative expenditure

The Company has entered into a number of contracts with third parties to perform services. These services primarily relate to investor relations. The Company had non-cancellable sales, general and administration commitments at June 30, 2009 of $81,154 that are payable in 2010 and $48,068 that are payable in 2011 and 2012. These costs are included in sales, general and administrative expense as incurred.

(c) Lease expenditure commitments

Operating lease commitments include leases of the building of the Company s principal office in Newstead, a suburb of Brisbane, Queensland, Australia, a manufacturing facility in Southport, Queensland, Australia, as well as the Company s US office in Emeryville, California, United States of America.

In 2009, on expiry of the lease, the Company vacated the building in Newstead, Queensland and entered a lease for new premises also located in Newstead, Queensland. The term of the new lease is seven years, and rental payments are subject to annual review based on the greater of CPI or 4%.

The first term of the Southport lease agreement expired in March 2007 and a three year option to extend the term was exercised. The agreement was then renegotiated in May 2007 for a five year term with an option for an additional five years. Under the terms of the Southport lease agreement, rental payments are subject to annual review based on the greater of CPI or 3%.

The Company entered into a lease of premises in Emeryville, California in December 2006 for a five year term to begin upon occupancy of the completed premises, with an option for renewal for a further

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three years. The Company took up occupancy in August, 2007. Under the terms of the lease, the rent is subject to a 3% fixed increase each year.

The operating leases are under normal commercial operating lease terms and conditions.

Rent expense has been incurred as follows:

	Years ended June 30,		
	2009	**2008**	**2007**
Rent expense	$ 567,069	$ 533,301	$ 170,581

The total minimum annual rentals under non-cancellable operating leases as at June 30, 2009 are as follows:

2010	$ 668,483
2011	$ 753,254
2012	$ 773,634
2013	$ 427,194
2014	$ 415,928
Thereafter	$ 804,971
Total	$ 3,843,464

(d) Government research grants

The Company has received two Australian Government research grants under the R&D START Program. The programs were completed by June 30, 2000 and August 31, 2004. For the period to August 31, 2009 the Australian Government may require the Company to repay all or some of the amount of a particular grant together with interest in either of the following circumstances:

The Company fails to use its best endeavors to commercialize the relevant grant project within a reasonable time of completion of the project; or

Upon termination of a grant due to breach of agreement or insolvency.

Technical failure of the grant funded project does not, in and of itself, constitute failure to use best efforts to commercialize the relevant grant project. The grants funded certain aspects of the Company s PEP005 project. The Company is continuing the project funded by the START Program. The Company believes that the likelihood of being required to repay grant funding on or before August 31, 2009 is remote while the Company continues to act in good faith with respect to its current and on-going efforts to commercialize projects funded by these grant programs. The total amount received under the START Program was $2,130,791.

(e) Other

As disclosed in Note 1, the collaboration with Allergan for the development and commercialization of PEP005 Gel was discontinued in October 2004. Under the terms of an agreement to terminate the collaboration, should Peplin relicense PEP005 Gel to another party, Peplin will pay Allergan 25% of pre-commercialization payments in the nature of license fees it receives subject to a cap of $3.0 million, and 25% of post commercialization royalties and similar revenue subject to a cap of $4.0 million, however, the combination of pre-commercialization license fees and post-commercialization royalties will not exceed $4.0 million. Alternatively, if Peplin itself markets PEP005 Gel in North and South America, Peplin will pay Allergan up to $4.0 million by way of a 10% royalty. There are no amounts accrued for in the financial statements as a result of the termination agreement.

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Under agreements with Queensland Institute of Medical Research (QIMR), Peplin has agreed to pay royalties of 0.6% of gross revenue to be derived in the future from intellectual property arising from certain research concerning HIV and protein kinase C conducted by QIMR on behalf of the Company. No royalties have been paid under this agreement from inception through June 30, 2009.

In November 2003, Peplin acquired a patent portfolio of intellectual property from Biolipids Pty Ltd (Biolipids). Under the terms of the acquisition, Peplin made an initial payment of cash, common stock and options over common stock. In addition, Peplin agreed to a series of future contingent payments, payable in common stock, relating to key milestones in the development and commercialization of compounds in the patent portfolio. At June 30, 2005 and at June 30, 2006 the Company determined that the Biolipids patents were impaired resulting in impairment loss of $210,387 and $77,626 for the years ended June 30, 2005 and 2006, respectively. At June 30, 2008 and 2009, the carrying value of the patents is zero.

During 2006, Peplin renegotiated the terms relating to the future contingent milestone payments in consideration for the re-assignment of certain patents to an associate of Biolipids. These patents related to intellectual property outside of Peplin s core focus in cancer and pain topical drug treatment. Under the terms of the revised agreement, Peplin may elect to make milestone payments in cash or common stock and these payments are capped as to value and number of shares or cash. The maximum number of shares capable of allotment under this revised agreement is 63,295 shares of common stock with a maximum market value of shares issued of $837,601. At June 30, 2009, no milestone payments are due or payable under this agreement.

Note 10: Acquisition of Neosil

Effective October 16, 2008, the Company acquired Neosil, a privately held, dermatology-focused company, in an all stock transaction. The agreed purchase price of $6.7 million was settled with a fixed number of the Company s common stock. Following the close of the transaction, Neosil became the Company s wholly-owned subsidiary. In addition to its primary asset, net cash and investments of $6.7 million, Neosil also owns an intellectual property portfolio which comprises two early clinical stage development programs: the first, a hair growth stimulation technology with potential application in the treatment of hair loss and the second, a broad spectrum anti-microbial technology with potential application in the treatment of acne.

The Company determined the stock to be issued to the Neosil stockholders based on Neosil s estimated fair value of $6.7 million. The number of shares was then calculated using the Company s volume weighted average closing price of the Company s CDIs, on the ASX in the 10 day period ended June 9, 2008 (being the last business day before the merger agreement was signed and announced to ASX), multiplied by twenty (being the rate of conversion of CDIs to common stock) and multiplied by the prevailing U.S. dollar to Australian dollar exchange rate as of that date. The shares were issued on October 16, 2008 at a share price of $4.68 which was calculated as the closing price of the Company s CDIs on the ASX on October 16, multiplied by twenty (being the rate of conversion of CDIs to common stock) multiplied by the U.S. dollar to Australian dollar exchange rate as of that date.

The acquisition of Neosil, a development stage company, was accounted for as an acquisition of assets rather than as a business combination in accordance with the criteria outlined in EITF 98-3 *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business*. The results of operations of Neosil were included in the Company s financial statements from October 16, 2008.

The fair values of the tangible net assets acquired were as follows:

	At October 16, 2008 (in thousands)
Cash	$ 4,389
Available-for-sale securities	2,243
Other receivables	112

Assumed liabilities		(100)
Total fair value of assets acquired, net of liabilities assumed	$	6,644

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At this time, the Company has not allocated any value to the intellectual property portfolio as the ability of the Company to successfully commercialize these products is highly uncertain. It is expected to take a number of years to conduct the necessary studies to file for product approval with the Food and Drug Administration, or FDA, and there is no assurance that such studies will be successful.

The Company intends to use the net cash obtained from the acquisition to continue the development of its lead product candidates PEP005 Gel for AK and PEP005 Gel for BCC.

Note 11: Stockholders equity

Issues of common stock

On May 23, 2007, the Company issued 2,500 shares of common stock at approximately $11.60 (A$14.00) per share in consideration of milestone payments for services performed in relation to the operation of the Southport manufacturing facility. The fair value of $35,046 was calculated by using the value of the services provided.

On September 11, 2007, the Company issued 762,722 shares of common stock at approximately $15.00 (A$18.00) per share to certain investors that entered into subscription agreements with the Company, raising $11,408,799 in cash. The total capital raising costs attributable to this issue was $325,868.

On October 5, 2007, the Company issued 348,389 shares of common stock at approximately $16.20 (A$18.00) per share to a related party that entered into a subscription agreement with the Company, raising $5,642,645 in cash. The total capital raising costs attributable to this issue was $166,888.

On October 16, 2008, the Company issued 819,378 shares of common stock for the acquisition of Neosil. The number of shares issue was based on Neosil s estimated fair value of $6.7 million using the Company s volume weighted average CDI closing price on the ASX in the 10 day trading period ended June 9, 2008, the date the Neosil merger agreement was signed.

On October 23, 2008, the Company completed a private placement with various institutional investors and issued an aggregate of 3,980,259 shares of common stock at $6.05 per share and warrants to purchase 1,326,753 shares of common stock. Gross proceeds received were $24.1 million. The total capital raising costs attributable to this issue was $3,118,636. As part of the agreement, for each three shares of common stock acquired, investors received a warrant to purchase one share of common stock. The warrants have an exercise price of $7.86 and expire on October 12, 2012.

In connection with the private placement, the Company also agreed to file a registration statement under the Securities Act of 1933, as amended, registering for resale the shares of common stock sold in the private placement, including the shares of common stock underlying the warrants. The registration statement was declared effective by the SEC on December 11, 2008. The Company may be liable for liquidated damages to holders of the common shares if the Company does not maintain the effectiveness of the registration statement. The amount of the liquidated damages is, in aggregate, 1.0% of the aggregate purchase price per month to a maximum of 12% of the aggregate purchase price paid by the investors for all common stock and warrants acquired.

Common stock

At June 30, 2009, the Company had authorized and outstanding 100,000,000 and 15,371,121 shares of common stock, respectively. Each share of common stock is entitled to one vote. The holders of

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common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors.

At June 30, 2009, the Company had 1 share of Class B common stock authorized and no shares issued and outstanding. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors. No dividends have been declared as of June 30, 2009.

Preferred stock

At June 30, 2009, the Company had 10,000,000 authorized shares of preferred stock, and no issued and outstanding. The holders of preferred stock are not entitled to vote or receive notice of any meeting of stockholders.

Note 12: Share-based payments

Corporate reorganization

On October 16, 2007 the Company had a restructuring event. This transaction was accounted for as a reorganization among entities under common control and the historical consolidated financial statements have been prepared as if the reorganization had occurred retroactively.

Prior to the reorganization, Peplin Limited had 15,861,460 employee options issued under the Peplin Limited Employee Share Option Plan (the Plan). These options were not dealt with as part of the court approved reorganization by private treaty between Peplin and the employee. On October 1, 2007, the Peplin, Inc. Incentive Award Plan (the Incentive Plan) was approved by special resolution of shareholders and effectively replaced the Plan. On October 31, 2007, all options outstanding under the Plan as of that date were cancelled and reissued under the Incentive Plan. The Company applied the guidance specified in SFAS 123(R) to evaluate whether the equity restructuring and modification of awards resulted in an increase in the fair value of such awards and whether additional compensation costs should be recognized. The Company evaluated the effect of the reorganization on the fair value of existing stock options immediately before and after the modification date, and determined that the impact was not material.

Accordingly, the employee options issued and outstanding under the Plan became 793,073 options under the Incentive Plan, in a 20:1 reverse split, which has been applied retroactively.

Peplin, Inc. Incentive Award Plan

The establishment of the Incentive Plan was approved by shareholders on October 1, 2007. All employees and directors of the Company and its subsidiaries and certain contractors are eligible to participate in the Incentive Plan upon nomination by the directors.

Under the Incentive Plan:

At June 30, 2009 the aggregate number of shares of common stock that may be made available for issuance under the plan is 2,500,000. This amount increased by 1,000,000 from 1,500,000 on October 6, 2008, when shareholders approved the increase at the Annual General Meeting;

The maximum number of shares of common stock with respect to one or more awards that may be granted to any one employee, consultant or non-employee director during any fiscal year shall not exceed the award limit of 500,000, as approved by the board of directors on October 5, 2008;

Awards that may be issued include options, restricted stock awards, restricted stock unit awards, performance awards, dividend equivalents awards, deferred stock awards, stock payment awards or stock appreciation rights;

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Optionholders shall not be, nor have any of the rights, dividends or other privileges of, stockholders of the Company in respect of any shares purchasable upon the exercise of any part of an option unless and until such shares have been issued by the Company to such holders;

Options are only exercisable or distributable while the holder is an employee, consultant or non-employee director, as applicable;

Options issued under the Incentive Plan will immediately lapse if an eligible employee is lawfully terminated or resigns, and may be affected by the death, disability or redundancy of an eligible employee;

The terms of the option shall not be more than ten years from the date the option is granted, and the exercise price is the closing share price as of the date of grant of the options;

The grant date represents the date where all terms are approved by the board of directors;

The measurement date represents the earlier of the date at which the commitment for performance to earn the equity instruments was reached or the date at which the counterparty s performance is complete;

Options are issued under the Incentive Plan for no cash consideration, each convertible into one share of common stock; and

Upon exercise of options, shares of common stock will be issued out of authorized common stock.

The following is a summary of options granted under the Incentive Plan from October 1, 2007:

	No. options	**Fair value**
October 31, 2007	793,073	$ 5,606,222
November 23, 2007	21,000	161,341
December 3, 2007	166,590	1,329,271
January 16, 2008	56,119	433,578
June 12, 2008	13,000	47,734
October 6, 2008	385,000	1,378,381
November 8, 2008	219,000	532,016
December 24, 2008	199,276	595,251
February 9, 2009	30,000	160,554
June 5, 2009	5,000	36,191
	1,888,058	$ 10,280,539

The following table summarizes the movements in options outstanding to employees and contractors under the Incentive Plan outstanding as of June 30, 2009:

	Number of ptions outstanding	**Weighted average exercise price**	**Weighted average fair value**
Total options at June 30, 2007			

- granted	1,049,782	$ 14.46	
- forfeited	(105,245)	$ 14.05	
- expired			
- exercised			
Total options at June 30, 2008	944,537	$ 14.51	$ 7.33
- granted	838,276	$ 5.37	
- forfeited	(148,518)	$ 13.60	
- expired	(245,757)	$ 13.62	
- exercised	(5,000)	$ 6.57	
Total options at June 30, 2009	1,383,538	$ 8.94	$ 4.70
Options exercisable at June 30, 2009	616,284	$ 11.08	$ 5.23
Options exercisable at June 30, 2008	482,906	$ 14.81	$ 6.59

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PEPLIN, INC.
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The following is a summary of options exercised during the period July 1, 2007 to June 30, 2009:

Exercise date	No. options	Exercise price	Total cash received
June 15, 2009	5,000	$6.57	$32,869
	5,000		

The weighted average grant-date fair value of options granted during the year was as follows:

2007	$ 0
2008	$7.22
2009	$3.22

The total weighted average intrinsic value of options exercised during the year was as follows:

2007	$ 0
2008	$ 0
2009	$16,948

The following table summarizes information about options under the Incentive Plan outstanding at June 30, 2009:

	Options outstanding		Options exercisable	
Weighted Average Exercise Price $	Number	Weighted Average Remaining Contractual Term	Number	Weighted Average Remaining Contractual Term
18.54	10,000	0.24	10,000	0.24
8.16	10,967	0.50	10,967	0.50
12.79	9,300	1.50	9,300	1.50
15.58	67,500	1.98	67,500	1.98
12.79	25,000	2.50	25,000	2.50
12.98	42,500	2.11	42,500	2.11
12.98	13,000	2.50	13,000	2.50
15.95	36,000	2.50	36,000	2.50
14.09	11,500	2.78	7,667	2.78
12.98	2,500	2.90	2,500	2.90
15.95	500	2.95	334	2.95
15.95	97,000	2.95	68,000	2.95
16.32	17,000	3.08	5,668	3.08
16.13	12,000	3.25	4,000	3.25
14.46	15,000	3.12	5,000	3.12
13.10	6,000	8.40	2,382	8.40
13.81	137,215	8.43	51,764	8.43
13.27	25,000	8.55	8,855	8.55
7.37	10,000	8.95	10,000	8.95
6.24	385,000	9.27	172,500	9.27

3.86	219,000	9.39	31,941	9.39
4.81	196,556	9.49	24,734	9.49
8.03	30,000	9.62	6,672	9.62
10.77	5,000	9.93	0	9.93
	1,383,538		616,284	
Aggregate Intrinsic value	$ 2,588,350		$ 631,712	

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PEPLIN, INC.
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A summary of the Company s non-vested options under the Incentive Plan as of June 30, 2009 are as follows:

Non-vested Options	Number	Weighted average grant date fair value	Weighted average remaining contractual period
Non-vested options at June 30, 2007			
Granted	1,049,782	$ 7.22	
Vested	(521,481)	$ 6.61	
Forfeited	(66,670)	$ 7.00	
Non-vested options at June 30, 2008	461,631	$ 7.74	6.42 years
Granted	838,276		
Vested	(408,126)		
Forfeited	(124,527)		
Non-vested options at June 30, 2009	767,254	$ 4.14	8.74 years

Weighted average grant date fair value of options vested:	
2009	$ 4.51
2008	$ 6.61
Total unrecognized cost of non-vested shares	
2009	$ 1,526,352
2008	$ 1,884,262

The total fair value of options vested during the year was as follows:

2008	$1,536,305
2009	$1,841,143

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Other share-based payment awards under the Incentive Plan

Non-vested shares

During the year ended June 30, 2009, the Company granted 225,000 shares of restricted stock to an employee subject to vesting and a repurchase right in favor of the Company if the employee ceases to be employed by the Company. The fair value of the non-vested shares of $6.24 per share was determined using the closing market price of the Company s CDIs multiplied by 20, converted at the US dollar exchange rate published by the Reserve Bank of Australia on grant date.

The total fair value of the unvested shares was $1,404,001. 56,250 shares vested on June 30, 2009, with a fair value of $351,000. At June 30, 2009 there 168,750 shares remain unvested, of which 56,250 shares will vest on June 30, 2010, and the remaining shares will vest on either June 30, 2011 or on the first day after twenty consecutive days during which the volume-weighted average price of the Company s common stock on each day is equal to or greater than $15.00 per share. Vesting is subject to continued employment with the Company.

At June 30, 2009, there was $710,161 of total unrecognized compensation cost relating to the remaining 168,750 unvested shares granted under the Incentive Plan. That cost is expected to be recognized over a weighted average period of 1.61 years.

Non-employee share-based payments

In December 2007, the Company issued 58,987 warrants with an exercise price of $15.26 to GE on entry into a loan agreement for borrowing of $15 million. The warrants vested immediately on the grant date, being December 28, 2007 (refer to Note 8).

The fair value of these warrants was estimated to be $452,985 using the Black Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 53.10%; risk free interest rate of 6.64%; and an expected life of 5.01 years. The options vested immediately, and therefore a non-cash amount of $452,985 has been recorded against contributed equity with the cost recorded as a borrowing cost in the balance sheet which will be amortized over the life of the loan.

During the year ended June 30, 2009, two officers of the Company resigned from the Company. Upon resignation both officers entered into consulting agreements with the Company. As the status of both officers changed from employee to non-employee, the accounting treatment of options held by these former officers changed to be in accordance with Issue 96-18 *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. (Issue 96-18), rather than SFAS 123R.

One agreement provided for consulting services to May 15, 2009, and became effective on August 15, 2008. At the date of resignation, 229,675 options were held by the officer and were treated as follows:

15,000 unvested options issued under the original employment agreement were forfeited on resignation with $79,854 of previously recognized compensation expense reversed on that date;

33,334 vested options issued under the Incentive Plan were cancelled on resignation;

16,666 unvested options issued under the Incentive Plan were forfeited on resignation with $83,457 of previously recognized compensation expense reversed on that date;

85,000 vested options issued under the original employment agreement were exercisable for a period of 270 days from the resignation, being May 12, 2009, and expired on that date;

39,950 vested options issued under the Incentive Plan were exercisable through the consulting period, with 5,000 being exercised and the remaining 34,950 options expiring at the completion of the consulting period;

39,725 options issued under the Incentive Plan continued to vest in accordance with the original option term. 18,341 vested during the consulting period with $12,514 of compensation expense being recognized in the

statement of operations. The remaining 21,384 options that were unvested at the completion of the consulting period resulted in $31,488 of previously recognized compensation expense being reversed out of the statement of operations on that date.

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The net effect on the statement of operations was $(182,285), with $1,169 of compensation expense being recognized over the consulting period. At the completion of the consulting period, 5,000 options were exercised, and the remaining options expired.

The second agreement provided for consulting services to June 15, 2009, and became effective on September 2, 2008. At the date of resignation, 108,469 options were held by the officer of which 40,386 were unvested and therefore were forfeited on that date. The total previously recognized compensation expensed reversed on that date was $191,251. The remaining 68,083 vested options were exercisable throughout the consulting period and expired on completion of the consulting period with no options being exercised.

In February 2009, the Company issued 10,000 options each to two contractors for services to be provided. The exercise price of the options was $8.03 per share, vesting in twelve equal monthly installments with the first monthly installment vesting on March 9, 2009. The options expire on February 8, 2019.

The fair value of the options was determined in accordance with SFAS 123(R), while the date at which to measure the fair value of the options was determined in accordance with EITF 96-18. As there is no performance commitment in place, measurement is determined to occur when the services are provided, being the date the options vest. Given that the options vest monthly, the fair value of the options will be remeasured monthly. As at June 30, 2009 the options were revalued and the fair value of the options were adjusted accordingly. Should the consultants discontinue their provision of services, no benefit from the remaining unvested options would be obtained, and hence no further compensation cost would be expensed in the statement of operations.

Peplin Limited Employee Share Option Plan

The establishment of the Plan was approved by special resolution of shareholders on June 30, 2000. All employees and directors of Peplin Limited and its subsidiaries and certain contractors were eligible to participate in the Plan upon nomination by the directors.

On October 1, 2007 the Incentive Plan was approved by special resolution of shareholders and effectively replaced the Plan. On October 31, 2007, all options outstanding under the Plan as of that date were cancelled and reissued under the Incentive Plan.

The following is a summary of options granted under the Plan from July 1, 2006 through to cancellation on October 31, 2007:

	No. options	**Fair value**
December 12, 2006	86,000	$ 493,575
June 12, 2007	500	3,113
	86,500	$ 496,688

The following is a summary of options exercised under the Plan from July 1, 2006 to October 31, 2008:

Exercise date	**No. options**	**Exercise price (AUD)**	**Exercise price (USD)**
September 4, 2007	167	$13.80	$11.35
	167		

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The following table summarizes the movements in options outstanding under the Plan as of June 30, 2007 and 2008:

	Number of options outstanding	Weighted average exercise price	Weighted average fair value
Total options at June 30, 2006	73,323	$ 11.40	$4.60
- granted	86,500	$ 13.60	
- forfeited	(1,750)	$ 12.80	
- expired	(27,500	$ 14.80	
- exercised			
Total options at June 30, 2007	130,573	$ 13.60	$5.60
- granted			
- forfeited	(333)	$ 12.08	
- expired			
- exercised	(167)	$ 12.08	
- cancelled	(130,073)	$ 14.75	$6.14
Total options at June 30, 2008		$	$
Options exercisable at June 30, 2008		$	$
Options exercisable at June 30, 2007	67,121	$ 12.80	$5.00

The weighted average grant-date fair value of each option granted during the year ended June 30, 2008 was $0 (year ended June 30, 2007: $5.80). The weighted average grant-date fair value of options vested during the year ended June 30, 2008 was $7.63. The total intrinsic value of options exercised during the year ended June 30, 2008 was $0 (years ended June 30, 2007: $0).

At June 30, 2008, $0 (June 30, 2007: $234,991) of total unrecognized compensation cost relating to non-vested options granted.

The total fair value of options vested for the year ended June 30, 2008 was $3,816 (during the years ended June 30, 2007 $202,405).

There were no options outstanding at June 30, 2008. The following table summarizes information about the Plan outstanding at June 30, 2007:

	Options outstanding		Options exercisable	
Weighted Average Exercise Price $	Number	Weighted Average Remaining Contractual Term	Number	Weighted Average Remaining Contractual Term
12.60	3,000	2.00	2,500	2.00
17.00	10,000	2.24	10,000	2.24
7.40	15,968	2.50	15,800	2.50
11.80	15,855	3.50	10,404	3.50
11.80	500	4.50	167	4.50

14.60	84,750	4.50	28,250	4.50
14.60	500	4.97		4.97
	130,573	3.91	67,121	3.44
Aggregate Intrinsic value	$ 26,259 88		$ 25,836	

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PEPLIN, INC.
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A summary of the Company s non-vested options as of June 30, 2007 and 20008 are as follows:

Non-vested Options	Number	Weighted average grant date fair value
Non-vested options at June 30, 2006	17,803	$ 4.40
Granted	86,500	$ 5.80
Vested	(39,852)	$ 5.00
Forfeited	(1,000)	$ 9.60
Non-vested options at June 30, 2007	63,451	$ 6.40
Granted		$
Vested	(500)	$ 7.20
Forfeited	(333)	$ 5.32
Cancelled	(62,618)	$ 6.91
Non-vested options at June 30, 2008		$

Other share-based payment options to employees and contractors

Other share-based payment options are also granted outside the Plan. These include options granted for services rendered from certain eligible contractors as approved by the directors, or as part of a director s or officer s sign-on remuneration prior to becoming a director or officer.

On October 1, 2007 the Incentive Plan was approved by special resolution of shareholders. On October 31, 2007, all shares granted outside the Plan as of that date were cancelled and reissued under the Incentive Plan.

The following is a summary of options granted outside the Plan from July 1, 2006 through to cancellation on October 31, 2007:

	No. options	Fair value
October 12, 2006	60,000	267,211
October 14, 2006	135,500	665,540
February 13, 2007	17,500	107,958
April 11, 2007	101,500	537,091
May 23, 2007	2,500	15,566
June 11, 2007	97,000	605,563
July 31, 2007	17,000	116,552
August 14, 2007	30,000	215,149
September 30, 2007	12,000	79,842
	565,500	$ 2,994,450

There were no options exercised outside the Plan from July 1, 2004 to June 30, 2008.

The following table summarizes the movements in options granted to employees and contractors outside the Plan outstanding as of June 30, 2007, and 2008:

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	Number of options outstanding	Weighted average exercise price	Weighted average fair value
Total options at June 30, 2006	234,415	$ 13.00	$5.80
- granted	414,000	$ 12.00	
- forfeited		$	
- expired	(26,915)	$ 14.78	
- exercised		$	
Total options at June 30, 2007	621,500	$ 13.60	$6.00
- granted	59,000	$ 14.47	
- forfeited	(17,500)	$ 14.53	
- expired		$	
- exercised		$	
- cancelled	(663,000)	$ 14.85	$6.60
Total options at June 30, 2008		$	$
Options exercisable at June 30, 2008		$	$
Options exercisable at June 30, 2007	245,833	$ 14.00	$5.80

The weighted average grant-date fair value of each option granted during the year ended June 30, 2008 was $7.58 (years ended June 30, 2007: $5.40). The weighted average grant date fair value of options vested during the year ended June 30, 2008 was $10.03 (year ended June 30, 2007: $4.80). The total intrinsic value of options exercised during the year ended June 30, 2008 was $0 (years ended June 30, 2007: $0).

The total fair value of options vested during the year ended June 30, 2008 was $150,385 (years ended June 30, 2007: $608,260).

At June 30, 2008 there was $0 (June 30, 2007: $1,594,595) of total unrecognized compensation cost relating to non-vested options granted outside the Plan.

There were no options outstanding at June 30, 2008. The following table summarizes information about options outside the Plan outstanding at June 30, 2007:

	Options outstanding		Options exercisable	
Weighted Average Exercise Price $	Number	Weighted Average Remaining Contractual Term	Number	Weighted Average Remaining Contractual Term
14.40	15,000	3.28	15,000	3.28
17.00	85,000	3.28	55,000	3.28
13.00	15,000	1.49	15,000	1.49
14.20	67,500	3.98	67,500	3.98
11.80	25,000	4.50	8,333	4.50
11.80	195,500	4.31	72,500	4.31
14.00	17,500	4.62		

13.00	101,500	4.76	10,000	4.76
11.80	2,500	4.89	2,500	4.89
14.60	97,000	4.97		
	621,500	4.24	245,833	3.78
Aggregate Intrinsic value	$ 71,327 90		$ 49,189	

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A summary of the Company s non-vested options outside the Plan as of June 30, 2007 and June 30, 2008 are as follows:

Non-vested Options	Number	Weighted average grant date fair value
Non-vested options at June 30, 2006	87,500	$ 6.00
Granted	414,000	$ 5.40
Vested	(125,833)	$ 4.80
Forfeited		$
Non-vested options at June 30, 2007	375,667	$ 6.20
Granted	59,000	$ 7.15
Vested	(15,000)	$ 9.46
Forfeited	(17,500)	$ 6.39
Cancelled	(402,167)	$ 6.66
Non-vested options at June 30, 2008		$

Other information

Options issued under the Incentive Plan generally have a five or ten year term. Options granted under the Incentive Plan which replaced options granted under the Plan (Replacement Grants) have the same life as those granted under the Plan as at October 31, 2007. Replacement grants vest in three equal annual tranches with first vesting depending on whether the options are sign-on options, where first vesting is on the anniversary of commencement, or performance remuneration options, where first vesting is on grant date. For options issued under the Incentive Plan, sign-on options vest to 25% of the options on the first anniversary of the grant date with the remaining 75% vesting in equal monthly installments from one month after the first anniversary date until the fourth anniversary of the grant date, and performance remuneration options vest in 48 equal monthly installments.

The fair value of all options granted to employees, directors and contractors were computed using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years ended June 30,		
	2009	2008	2007
Risk free interest rate	3.18%	4.11%	5.97%
Expected dividend yield	0%	0%	0%
Expected term	6.02 years	3.34 years	2.62 years
Expected volatility	65%	61%	52%
Expected forfeiture	11.78%	2.67%	1.17%

The Black-Scholes option pricing model was developed for use in estimating the fair value of options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. The expected term of the options used in the estimation of the fair value of non-traded options has been determined based on the mid point between the vesting date and the end of the contractual term. For those options issued prior to June 30, 2006, the Company has utilized an average volatility based on guideline companies within the biotechnology sector as there was sufficient company trading history in order to determine an accurate volatility rate. For options issued subsequent to June 30, 2006 through to the date of the Reorganization, the Company has calculated expected volatility based on the Company s

own trading

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activity data. Upon the Reorganization, primarily due to the underlying security changing from an Australian ordinary share to US common stock, the Company began to use US risk free interest rates, and volatilities based on NASDAQ-listed peer companies within the biotechnology sector.

The stock-based compensation expense has been recorded in the following captions of the consolidated statements of operations:

	Years ended June 30,		
	2009	**2008**	**2007**
Research and development	$ 971,858	$ 1,447,729	$ 553,078
Sales, general and administration	1,630,000	756,010	780,002
Total	$ 2,601,858	$ 2,203,739	$ 1,333,080

Note 13: Segment disclosures

The Company operates in one business segment. Its activities comprise of research and development of the therapeutic products for the treatment of cancers and other diseases, from which it derives no customer revenue. The Company operates in two geographical areas being Australia and the United States, with total assets as follows:

	June 30,	
	2009	**2008**
Australia	$ 15,118,698	$ 33,852,068
United States	8,244,809	2,117,028
	$ 23,363,507	$ 35,969,096

Note 14: Fair value of financial instruments

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, or an exit price. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques involve some level of management estimation and judgment, the degree of which is dependent on several factors, including the instruments complexity.

Beginning July 1, 2008, assets and liabilities recorded at fair value are categorized based upon the level of judgment associated with inputs used to measure their value. SFAS 157 defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market date for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In accordance with SFAS 157, the following table represents the Company s fair value hierarchy for its financial assets and liabilities (cash and short-term deposits) measured at fair value on a recurring basis as of June 30, 2009:

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Description	June 30, 2009	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash	$ 11,022,577	$ 11,022,577	$	$
Money market funds	6,728,512	$	$ 6,728,512	$
Total	$ 17,751,089	$ 11,022,577	$ 6,728,512	$

Note 15: Employee benefit plan

As required by Australian law, the Company contributes to defined contribution superannuation funds on behalf of all Australian employees at the rate of 9% of employee salaries. The Company elects to contribute an additional 1%, making the total contribution 10%. The Company contributed $118,817, $182,916 and $178,387 to superannuation funds for the years ended June 30, 2007, 2008 and 2009.

Note 16: Quarterly Financial Information (unaudited)

Selected quarterly financial data for fiscal years 2009 and 2008 were as follows:

	Year ended June 30, 2009			
	First	Second	Third	Fourth
Net loss	$ (10,202,927)	$ (12,645,885)	$ (7,202,370)	$ (13,816,476)
Net loss attributable to common stockholders	$ (10,202,927)	$ (12,645,885)	$ (7,202,370)	$ (13,816,476)
Net loss per share basic and diluted	$ (0.99)	$ (0.90)	$ (0.48)	$ (0.91)

	Year ended June 30, 2008			
	First	Second	Third	Fourth
Net loss	$ (4,563,041)	$ (7,548,238)	$ (6,114,959)	$ (7,730,010)
Net loss attributable to common stockholders	$ (4,563,041)	$ (7,548,238)	$ (6,114,959)	$ (7,730,010)
Net loss per share basic and diluted	$ (0.49)	$ (0.73)	$ (0.59)	$ (0.75)

Note 17: Subsequent events

Agreement and Plan of Merger

On September 2, 2009, the Company, LEO and Plant Acquisition Sub, Inc., a wholly owned subsidiary of LEO (Acquisition Sub), entered into an Agreement and Plan of Merger (the Merger Agreement) pursuant to which Acquisition Sub will be merged with and into Peplin, with Peplin surviving the merger as a wholly owned subsidiary of LEO (the Merger). The consummation of the Merger is subject to the conditions set forth in the Merger Agreement, including adoption of the Merger Agreement by Peplin s stockholders, the requirement that less than 10% of Peplin s outstanding shares exercise their rights to dissent under the Delaware General Corporation Law, the requirement that certain persons enter into offer letters with LEO and remain employed at the closing, and other customary closing conditions.

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At the effective time of the Merger, each outstanding share of Peplin common stock will be converted into the right to receive an amount in cash equal to $16.99 per share (the Per Share Merger Consideration). In connection with the Merger, each outstanding and unexercised option and warrant will become fully vested and exercisable. Those options and warrants with a per share exercise price or purchase price, as applicable, that is less than the Per Share Merger Consideration will be automatically cancelled and converted into the right to receive an amount in cash equal to the difference between (a) the Per Share Merger Consideration multiplied by the number of shares of Peplin common stock underlying the option or warrant and (b) the aggregate exercise or purchase price, as applicable, of the option or warrant.

The Merger Agreement contains customary representations, warranties and covenants, including covenants restricting Peplin s conduct of its business between the date of the signing of the Merger Agreement and the closing of the Merger. The Merger Agreement may be terminated by the parties under certain circumstances. The Merger Agreement also provides for the payment of a termination fee of $10,000,000 to LEO in specified circumstances in connection with the termination of the Merger Agreement.

Voting Agreements

In connection with the Merger Agreement, the directors and executive officers of Peplin and certain affiliated investment funds, holding in the aggregate approximately 33.35% of the outstanding share of Peplin common stock, have entered into voting agreements pursuant to which they have agreed to, among other things, vote their shares of Peplin common stock in favor of the Merger. The parties to the voting agreements have agreed to comply with certain restrictions on the disposition of such shares, subject to the terms and conditions contained therein. Pursuant to their terms, such voting agreements will terminate upon the earlier to occur of the approval of the Merger by Peplin s stockholders and any termination of the Merger Agreement.

Loan Agreement

In connection with the Merger Agreement, Peplin and LEO entered into a Loan Agreement, dated as of September 2, 2009, pursuant to which LEO has agreed to provide loans to Peplin of up to an aggregate principal amount of $24,000,000. Advances bear interest at a rate per annum equal to the sum of the applicable one-month London Inter-Bank Offering Rate (LIBOR) for the U.S. dollar plus 2% until the termination of the Merger Agreement, and LIBOR for the U.S. dollar plus 9% thereafter. Peplin can request no more than one Advance in any 15-day period, and each advance cannot exceed the lesser of (a) $2,000,000 and (b) the amount of Peplin s budgeted cash expenditures and transaction expenses for the month, but in no event shall the aggregate principal amount of all outstanding Advances exceed the aggregate amount available under the Loan Agreement.

The Loan Agreement is unsecured and loans under the Loan Agreement are subordinated to loans pursuant to the Loan Facility.

The principal of, and accrued interest on, the Advances must be repaid on that date which is the earlier to occur of: (a) April 1, 2011; (b) the date that is seven days after the effective date of the Merger; (c) the date that is seven days after the consummation of an acquisition by Peplin by a third party other than LEO; and (d) the date that is six months after the termination of the Loan Facility.

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

None.

Item 9A(T). ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and discussed with our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, our disclosure controls and procedures may become inadequate because of changes in conditions, or a deterioration in the degree of our compliance with policies or procedures. Based on the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Our management, including our chief executive officer and chief financial officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report pursuant to Exchange Act Rule 13a-15(b) of the Exchange Act. Based on the evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective.

Internal Control over Financial Reporting

This Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Item 9B. ***Other Information***

None.

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PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Except as set forth below, the information required by this Item 10 is incorporated herein by reference to an amendment to this Form 10-K to be filed with the SEC not later than October 28, 2009.

We maintain a Code of Business Conduct and Ethics that incorporates our code of ethics applicable to all employees, including all officers. Our Code of Business Conduct and Ethics is published on the Corporate Governance section of our website at www.peplin.com. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions granted to such executive officers and directors, on this website within four business days following the date of such amendment or waiver.

Item 11. ***Executive Compensation***

The information required by this Item 11 is incorporated herein by reference to an amendment to this Form 10-K to be filed with the SEC not later than October 28, 2009.

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

The information required by this Item 12 with is incorporated herein by reference to an amendment to this Form 10-K to be filed with the SEC not later than October 28, 2009.

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

The information required by this Item 13 is incorporated herein by reference to an amendment to this Form 10-K to be filed with the SEC not later than October 28, 2009.

Item 14. ***Principal Accounting Fees and Services***

The information required by this Item 14 is incorporated herein by reference to an amendment to this Form 10-K to be filed with the SEC not later than October 28, 2009.

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PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a)(1) *Financial Statements:* The financial statements filed as part of this Form 10-K are listed on the index to financial statements on page 55.

(2) No financial statement schedules were required to be filed as part of this report because the required information is not present or is not present in amounts sufficient to require submission of the schedules or because the information required is included in the Consolidated Financial Statements or Notes thereto.

(b) *Exhibits.* The exhibits listed on the Exhibit Index (following the Signatures section of this report) are included, or incorporated by reference, in this Form 10-K.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Peplin, Inc.

Dated: September 28, 2009

By: /s/ Thomas Wiggans
Thomas Wiggans
Chief Executive Officer
(Principal Executive Officer)

Dated: September 28, 2009

By: /s/ David J. B. Smith
David J. B. Smith
Chief Financial Officer and Secretary
(Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas Wiggans as his attorney-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Thomas Wiggans	Chief Executive Officer and Chairman of Board	September 28, 2009
Thomas Wiggans	(Principal Executive Officer)	
/s/ David J.B. Smith	Chief Financial Officer and Secretary	September 28, 2009
David J.B. Smith	(Principal Financial Officer)	
/s/ Eugene Bauer	President, Chief Medical Officer and Director	September 28, 2009
Eugene Bauer		
/s/ Joshua Funder	Director	September 28, 2009
Joshua Funder		
/s/ Cherrell Hirst	Director	

		September 28, 2009
Cherrell Hirst		
/s/ Gary Pace	Director	September 28, 2009
Gary Pace		
/s/ James Scopa	Director	September 28, 2009
James Scopa		
/s/ Michael Spooner	Director	September 28, 2009
Michael Spooner		

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EXHIBIT INDEX

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger, dated as of September 2, 2009, by and among Peplin, Inc., LEO Pharma A/S and Plant Acquisition Sub, Inc. (incorporated by reference to Exhibit 2.1 to Peplin s current report on Form 8-K filed on September 2, 2009)
3.1	Certificate of Incorporation of Peplin, Inc. (incorporated by reference to Exhibit 3.1 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
3.2	Bylaws of Peplin, Inc. (incorporated by reference to Exhibit 3.2 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
4.1	Form of Common Stock certificate (incorporated by reference to Exhibit 4.1 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
4.2	Form of Class B Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
4.3	Form of Warrant Agreement, dated December 28, 2007 (incorporated by reference to Exhibit 4.3 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
4.4	Registration Rights Agreement, dated October 23, 2008 (incorporated by reference to Exhibit 4.4 to Registration Statement No. 000-53410 on Form 10/A filed on October 27, 2008)
4.5	Form of Warrant Agreement for Non-U.S. Persons, dated October 23, 2008 (incorporated by reference to Exhibit 4.5 to Registration Statement No. 000-53410 on Form 10/A filed on October 27, 2008)
4.6	Form of Warrant Agreement for U.S. Persons, dated October 23, 2008 (incorporated by reference to Exhibit 4.6 to Registration Statement No. 000-53410 on Form 10/A filed on October 27, 2008)
10.1	Implementation Agreement between Peplin Limited and Peplin, Inc., dated August 8, 2007 (incorporated by reference to Exhibit 10.1 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.2	2007 Incentive Award Plan (incorporated by reference to Exhibit 10.2 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.3	Amendment to the 2007 Incentive Award Plan (incorporated by reference to Exhibit 10.1 to the Company s 10-Q dated December 1, 2008)
10.4	Amendment No. 2 to the 2007 Incentive Award Plan (incorporated by reference to Exhibit 10.2 to the Company s 10-Q dated December 1, 2008)
10.5	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.6	

	Form of Indemnity Agreement for Directors and Officers (incorporated by reference to Exhibit 10.4 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.7	Purchase Agreement between Dr. Gary Pace and Peplin Limited, dated June 23, 2006 (incorporated by reference to Exhibit 10.5 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.8	Separation Agreement between Peplin, Inc. and Michael Aldridge, dated August 15, 2008 (incorporated by reference to Exhibit 10.6 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)

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Exhibit No.	Description of Exhibit
10.9	Employment Agreement between Peplin Limited, Peplin Operations USA, Inc. and Philip Moody, dated September 8, 2006 (incorporated by reference to Exhibit 10.7 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.10	Employment Agreement between Peplin Operations USA, Inc. and Cheri Jones, dated June 14, 2006 (incorporated by reference to Exhibit 10.01 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.11	Employment Offer Letter between Peplin, Inc. and David J.B. Smith, dated March 25, 2009 (incorporated by reference to Exhibit 10.01 to Peplin s current report on Form 8-K filed on March 30, 2009)
10.12	Employment Agreement between Peplin Limited and Peter Welburn, dated May 10, 2004 (incorporated by reference to Exhibit 10.12 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.13	Letter, dated December 15, 2006, from Peplin Limited to Peter Welburn regarding role change and salary adjustment (incorporated by reference to Exhibit 10.13 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.14	Employment Agreement between Peplin Operations USA, Inc. and George Mahaffey, dated May 22, 2007 (incorporated by reference to Exhibit 10.14 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.15	Employment Agreement between Peplin, Inc. and Eugene Bauer, MD, dated August 18, 2008 (incorporated by reference to Exhibit 10.15 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.16	Employment Agreement between Peplin, Inc. and Thomas Wiggans, dated August 15, 2008 (incorporated by reference to Exhibit 10.16 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.17	Lease between Peplin Biotech Ltd. and Pine Waters Pty Ltd., dated June 10, 2004 (incorporated by reference to Exhibit 10.17 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.18	Lease between Peplin Operations USA Inc. and Bay Centre Office LLC, dated December 22, 2006 (incorporated by reference to Exhibit 10.18 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.19	Lease between Peplin Operations Pty Ltd. and Garrels Investments Pty Ltd., dated May 28, 2007 (incorporated by reference to Exhibit 10.19 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.20	R&D Start Program Grant Agreement between Commonwealth of Australia acting through the Industry Research and Development Board and Peplin Operations Pty Ltd., dated September 19, 2003

	(incorporated by reference to Exhibit 10.21 to Registration Statement No. 000-53410 on Form 10 filed on September 12, 2008)
10.21	Termination and Settlement Agreement between Allergan Sales LLC and Peplin Ltd., dated October 7, 2004 (incorporated by reference to Exhibit 10.22 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.22	Form of Subscription Agreement dated, August 8, 2007 (incorporated by reference to Exhibit 10.23 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.23	Loan Agreement among Peplin Limited, the guarantors party thereto, General Electric Capital Corporation as agent for the lenders party thereto, General Electric Capital Corporation as security trustee and General Electric Capital Corporation and Oxford Finance Corporation as lenders, dated December 28, 2007 (incorporated by reference to Exhibit 10.24 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)

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Exhibit No.	Description of Exhibit
10.24	Guaranty, Pledge and Security Agreement among Peplin, Inc., Peplin Operations USA, Inc. and General Electric Capital Corporation as agent for the lenders, dated December 28, 2007. (incorporated by reference to Exhibit 10.25 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.25	Clinical Services Master Agreement between Peplin Operations Pty Ltd and Omnicare CR, Inc., dated June 1, 2005 (incorporated by reference to Exhibit 10.26 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.26	Development and clinical supply agreement between Peplin, Inc. and DPT Laboratories, Ltd., dated October 23, 2007 (incorporated by reference to Exhibit 10.27 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.27	Plan of Merger and Reorganization between Peplin, Inc., West Acquisitions Corp. and Neosil, Inc., dated June 9, 2008 (incorporated by reference to Exhibit 10.28 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.28	Stock Subscription and Registration Rights Agreement, dated August 18, 2008, by and among Peplin, Inc. and the investors named therein (incorporated by reference to Exhibit 10.29 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.29	Master Clinical Services Agreement between Peplin Operations Pty Ltd and TKL Research, Inc., dated April 7, 2008 (incorporated by reference to Exhibit 10.30 to Current Report No. 000-53410 on Form 10 filed on September 12, 2008)
10.30	Restricted Stock Award Agreement, dated November 6, 2008 (incorporated by reference to Exhibit 10.1 to the Company s Form 8-K dated November 6, 2008)
10.31	Loan Agreement between Peplin, Inc. and LEO Pharma A/S, dated as of September 2, 2009 (incorporated by reference to Exhibit 10.1 to Peplin s current report on Form 8-K filed on September 2, 2009)
10.32	Lease Agreement between Peplin, Inc. and The Public Trustee of Queensland as Custodian for Opus Capital Growth Fund No. 1, dated June 3, 2009
21.1	Subsidiaries of Peplin, Inc.
24.1	Power of Attorney (included in signature pages)
31.1	Certification of the Chief Executive Officer, as required pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer, as required pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	

	Certifications of the Chief Executive Officer and the Chief Financial Officer, as required pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and furnished herewith pursuant to SEC Release No. 33-8238	
99.1	Form of Voting Agreement by and between LEO Pharma A/S and each of the members of the Board of Directors and executive officers of Peplin, Inc. and affiliated stockholders (incorporated by reference to Exhibit 99.1 to Peplin s current report on Form 8-K filed on September 2, 2009)	

Management contract or compensatory plan or arrangement

Confidential treatment was requested and received for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934. In accordance with Rule 24b-2, these confidential portions were omitted from this exhibit and filed separately with the Securities and Exchange Commission.

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This certification is not deemed filed for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that Peplin, Inc. specifically incorporates it by reference.