

PEPLIN INC  
Form 424B3  
December 12, 2008  
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Filed Pursuant to Rule 424(b)(3)  
Registration No. 333-155801

**PROSPECTUS**

# Peplin, Inc.

## 6,221,947 shares of Common Stock

This prospectus covers the offer and resale by the selling stockholders identified in this prospectus of up to 5,365,999 shares of common stock, \$0.001 par value, of Peplin, Inc., which includes 3,980,259 shares of common stock issued by us to certain investors in a private placement and 1,385,740 shares of common stock underlying outstanding warrants. We refer to the shares of common stock covered by this prospectus as the Resale Securities. We will not receive any of the proceeds from the sale or other disposition of the Resale Securities by the selling stockholders. We will, however, receive proceeds from any warrants exercised for cash.

The selling stockholders or their pledgees, assignees or successors-in-interest may offer and sell or otherwise dispose of the Resale Securities described in this prospectus from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The selling stockholders will bear all commissions and discounts, if any, attributable to the sales of Resale Securities. We will bear all other costs, expenses and fees in connection with the registration of the Resale Securities. See Plan of Distribution beginning on page 106 for more information about how the selling stockholders may sell or dispose of their shares of the Resale Securities.

This prospectus also covers the exercise of options exercisable for 855,948 shares of our common stock and our issuance of up to 855,948 shares of common stock upon such issuance. The options were originally issued in July 2006 by our predecessor, Peplin Limited. In connection with the reorganization of Peplin Limited in October 2007 into us, we issued new options to acquire shares of our common stock in exchange for the Peplin Limited options. The options have a weighted average exercise price of \$13.05 per share and expire in October, 2010. We refer to these new options as the replacement options. Chess Depository Interests, or CDIs representing 1/20<sup>th</sup> of an interest in a replacement option are currently listed on the Australian Stock Exchange, or ASX, and trade under the symbol PLIO. On November 24, 2008, the closing price of the replacement option CDIs on the ASX was A\$0.05 per CDI. We will receive proceeds from the exercise of any replacement options.

There is no public market for the shares of our common stock in the United States. Currently, the beneficial ownership of our common stock is listed 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.

**Investing in our securities involves risks that are described in the Risk Factors section beginning on page 6 of this prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is December 12, 2008.

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You should rely only on the information contained in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. The selling stockholders are offering to sell, and seeking offers to buy, the Resale Securities only in jurisdictions where such offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, prospects, financial condition and results of operations may have changed since that date.

For investors outside the United States: Neither we nor any of the selling stockholders have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Peplin Pharmaceuticals for Life<sup>(R)</sup> is our registered trademark in the United States. PepTalk<sup>(R)</sup>, Peplin Pharmaceuticals for Life<sup>(R)</sup>, Peplin<sup>(R)</sup> and Peplin Biotech<sup>(R)</sup> are our registered trademarks in Australia. All other trademarks, tradenames and service marks appearing in this prospectus are the property of their respective owners.

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**PROSPECTUS SUMMARY**

*This summary highlights information about this offering and our business. It does not contain all of the information that may be important to you. You should read this entire prospectus and should consider, among other things, the matters set forth under the headings Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes thereto of Peplin, Inc., appearing elsewhere in the prospectus.*

**Our Company**

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, which is the first in a new class of compounds and is 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 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, for which we recently commenced a Phase III clinical trial, 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.

We are also developing a product candidate containing PEP005 for the treatment of superficial basal cell carcinoma, or superficial BCC. This product candidate is currently in Phase IIa clinical trials 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.

**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

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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.

### **Our Product Candidates**

#### *PEP005 Gel for AK*

We recently completed our PEP005-006 Phase IIb clinical trial of PEP005 Gel for AK as a field-directed therapy for non-facial AK lesions, including lesions on the scalp. Results from the trial of 222 patients suggest that the drug presents a favorable safety profile and is well tolerated at all tested doses. The trial involved a single application of either 0.025% or 0.05% of PEP005 gel each day, for two or three consecutive days. The most common side effects were local skin responses, such as redness, flaking or scaling and crusting. Local skin responses typically resolved in two to four weeks after completion of treatment. The trial evaluated three efficacy measures using various lesion clearance metrics. On the primary efficacy measure, the partial AK clearance rate, 75% of the patients in the highest dose group cleared three quarters or more of their lesions 57 days post-treatment and 56% of patients in the lowest dose group cleared three quarters or more of their lesions 57 days post-treatment. The two secondary efficacy measures were the complete AK clearance and the baseline AK clearance rate. In the highest dose group the complete AK clearance rate and baseline AK clearance rate were 54% and 58% of patients, respectively, and in the lowest dose group were 40% and 42% of patients, respectively. All of these clearance results were statistically significant when compared with the vehicle gel.

We also recently completed our PEP005-007 Phase IIa clinical trial of PEP005 Gel for AK as a field-directed therapy for AK in treatment locations on the face. This trial of 86 patients examined concentrations from 0.0025% to 0.025% PEP005 Gel for AK for two and three consecutive day dosing regimens. We believe that the results from this trial suggest that each dose of PEP005 Gel for AK studied at and below the maximum tolerated dose, or MTD, presents a favorable safety profile and is well tolerated. Based on these results, we plan to conduct a Phase IIb clinical trial to further study a range of doses from 0.005% to 0.015% PEP005 Gel for AK, applied daily for two or three consecutive days for further development in the treatment of AK lesions on head locations.

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;

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 recent PEP005-003 Phase IIa 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 II dose escalation clinical trial, which we call PEP005-009, in which we are increasing the dosage of PEP005 Gel for BCC to establish the 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 III clinical program for PEP005 Gel for BCC until 2010.

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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 short coming 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.

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While we believe PEP005 Gel for AK and PEP005 Gel for BCC offer advantages to other currently existing treatment options for AK or BCC, the potential side effects of these product candidates include redness, flaking or scaling, crusting, swelling, blistering, and ulceration. The side effects from these product candidates may last as long as four weeks or more. Moreover, patients may believe that treatment with products containing PEP005 will be uncomfortable or inconvenient. Physicians and patients may perceive that the side effects of our products outweigh the benefits of their use and, as result, may be unwilling to change their current treatment regimens. Furthermore, even if approved by the FDA, physicians may not prescribe our products until we do have long term data regarding their safety and efficacy.

## **Risk Factors**

Our business is subject to a number of risks, which you should be aware of before you decide to buy our common stock or warrants. In particular, you should consider the following risks, which are discussed more fully in Risk Factors beginning on page 6:

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. Our net loss for the year ended June 30, 2008 and the three months ended September 30, 2008 was \$25,956,248 and \$10,202,927, respectively. As of September 30, 2008, we had an accumulated deficit of \$82,265,770.

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

Our ability to timely and successfully complete a Phase IIb clinical trial related to PEP005 Gel for AK for head applications will be critical to advancing our regulatory approval process for head applications to the next phase of clinical development.

If we are not able to successfully complete a Phase III 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.

Even if our products receive regulatory approval, we may still face development and regulatory difficulties that may delay or impair future sales of our products and we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our products.

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 will develop.

## **Corporate Information**

We were incorporated in Delaware on July 31, 2007 as a wholly-owned subsidiary of Peplin Limited. Peplin Limited, originally Peplin Biotech Ltd., was initially formed as an Australian company in 1999. Our principal executive offices are located at 6475 Christie Avenue, Emeryville, California 94608. Our telephone number is (510) 653-9700, and our website address is [www.peplin.com](http://www.peplin.com). Information contained on our website is not a prospectus and does not constitute part of this prospectus.

## **The Offering**

Common stock being offered by the selling stockholders:

5,365,999 shares of common stock, including:

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3,980,259 shares of common stock currently held by certain of the selling stockholders; and

1,385,740 shares of common stock issuable upon exercise of warrants held by certain of the selling stockholders.

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Common Stock being offered by us: 855,948 shares of common stock issuable upon exercise of outstanding replacement options with a weighted exercise price of \$13.05 per share.

Use of Proceeds: We will not receive any proceeds from the sale of the Resale Securities by the selling stockholders in this offering.

We intend to use any proceeds we receive upon exercise of a replacement option or the warrants to further the development of our existing product candidates and for other general corporate purposes.



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Our functional currency for accounting purposes is the Australian dollar and our reporting currency is the U.S. dollar. All dollar figures contained in this prospectus are set forth in U.S. dollars, except as otherwise indicated. All Australian dollars translated into U.S. dollars have been translated at the following rates per A\$, except as otherwise indicated:

<b>Year Ended June 30,</b>		<b>For Revenues, Expenses and Compensation Numbers(1)</b>	<b>For Assets and Liabilities(2)</b>
	2008	\$ 0.9046	\$ 0.9626
	2007	\$ 0.7925	\$ 0.8491
	2006	\$ 0.7472	\$ 0.7423
	2005	\$ 0.7568	\$ 0.7618
	2004	\$ 0.7155	\$ 0.6952
<b>Three Months Ended September 30,</b>			
	2008	\$ 0.8894	\$ 0.7996
	2007	\$ 0.8750	\$ 0.8776

- (1) These exchange rates represent average exchange rates during the period.  
(2) These represent the exchange rates as of June 30 or September 30, as applicable.

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**RISK FACTORS**

*You should carefully consider the following risks, as well as all of the other information contained in this prospectus, any of which could materially affect our business, business prospects, cash flow, results of operations or financial condition. In assessing these risks, you should also refer to the other information contained in this prospectus, including our consolidated financial statements and related notes therein.*

**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 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 year ended June 30, 2008 and the three months ended September 30, 2008 was \$25,956,248 and \$10,202,927, respectively. As of September 30, 2008, we had an accumulated deficit of \$82,265,770. Net cash used in operating activities was \$10,054,261 during the three months ended September 30, 2008. 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 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 an early stage of 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 (ingenol mebutate) Gel for AK, or PEP005 Gel for AK, a topical gel for the treatment of actinic keratosis, or AK. We are not permitted to market PEP005 Gel for AK in the United States until we have submitted and received approval of a new drug application, or 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 2010, at the earliest.

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.

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**Our ability to timely and successfully complete a Phase IIb clinical trial related to PEP005 Gel for AK for head applications will be critical to advancing our regulatory approval process for head applications to the next phase of clinical development.**

Prior to filing an NDA for PEP005 Gel for AK, we will need to complete a series of clinical trials in head and non-head treatment locations. We believe the market for head applications of PEP005 Gel for AK is substantially larger than the market for non-head applications. Prior to initiating our Phase III clinical trial for head applications, we are conducting a Phase IIb dose ranging clinical trial for head applications, which initiated in June 2008. We believe this trial will help us determine the appropriate concentration of PEP005 Gel for AK for head field-directed therapy and will support the design of our subsequent Phase III clinical trial. Consequently, the results of our Phase IIb trial are critical to our advancement to a Phase III clinical trial program for head applications, and we do not expect to conduct our formal end-of-Phase II meeting with the FDA until our Phase IIb clinical trial is complete. Accordingly, we cannot assure you that the results from our proposed Phase IIb clinical trial will be sufficient to support our moving forward to the next phase of clinical development for head applications. Moreover, results from our recently completed Phase IIa clinical trial for applications on the face or from our completed Phase IIb clinical trial for applications on non-facial treatment locations, are not necessarily indicative of the results we will obtain in our Phase IIb clinical trial for head applications. Additionally, the FDA may continue to impose greater scrutiny on the results from our clinical trials for head applications, which include the face, as there may be a greater safety concern for the treatment of the face, and even if we believe the results from our Phase IIb clinical trial are favorable, the FDA may disagree.

If the results of our proposed Phase IIb clinical trial do not support the initiation of a Phase III clinical trial, we may alter our strategy with the FDA to initially seek approval for PEP005 Gel for AK only for non-head applications. If our only approved product is PEP005 Gel for AK for use in non-head applications, our potential market and our ability to commercialize that product would be substantially reduced, which would negatively impact our business.

**If we are not able to successfully complete a Phase III 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 larger future clinical trials. The FDA generally requires successful completion of at least two adequate and well-controlled Phase III clinical trials prior to the submission of an NDA. While we believe that our two proposed Phase III trials, one for head and one for non-head application, will serve as our two required adequate and well-controlled studies, the FDA upon reviewing the results of the trials may disagree and require us to conduct one or more additional Phase III 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.

We secured a clinical Special Protocol Assessment from the FDA with respect to the design and conduct of our Phase III clinical trial for non-head applications; however, we will not complete the design of our Phase III clinical trial for head applications until after our end-of-Phase II meeting with the FDA. Our Phase III clinical trials may not achieve positive results, and, even if we believe the results are positive, the FDA may disagree or the results may not adequately support or reproduce the results of any corresponding earlier clinical trial. If we fail to complete our Phase III clinical trials for PEP005 Gel for AK, or if these clinical trials fail to demonstrate with substantial evidence that PEP005 Gel for AK is both safe and effective, we will not be able to commercialize this product candidate in the United States or elsewhere and our business will be significantly harmed. Moreover, given that we have not conducted our formal end-of-Phase II meeting with the FDA, and we may not do so before we completing our Phase IIb clinical trials, we cannot assure you that our Phase IIb and Phase III clinical trials will not be materially modified or that, once completed, they will be sufficient to support a single NDA approval. For instance, based on correspondence with the FDA and guidelines recognized by the FDA, we expect that a carcinogenicity study for PEP005 Gel for AK will not be required to support our NDA filing. The FDA, however, may require us to complete a carcinogenicity study for PEP005 Gel for AK prior to filing an NDA in the event that our clinical use of PEP005 Gel for AK changes, for example, changes in our expected treatment regimen. If the FDA requires additional clinical trials, including additional supportive safety studies, to support an NDA, our ability to commercialize PEP005 Gel for AK may be further delayed or substantially reduced.

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**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 III 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 (ingenol mebutate) Gel for BCC, or PEP005 Gel for BCC. We are currently evaluating this product candidate when used as a tumor-directed therapy in a Phase II clinical trial designed to assess safety and dosage tolerance. We must complete this trial, and potentially others, before we can commence our Phase III clinical trials for this application. We expect that we will have to conduct two successful Phase III 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 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 cm<sup>2</sup>. 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;

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the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

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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 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 Therapeutics Goods Administration, or 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 Human Research Ethics Committee, or 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 current Good Manufacturing Practices, or 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.



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**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 clinical research organizations, or 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 institutional review board, or 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 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.**



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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

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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.**

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.

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If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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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;

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.

**The suspension or termination of our government research grants may result in lost revenue. We may also be required to repay previously received grant revenue in certain circumstances, which would have an adverse effect on our cash position, business, prospects, financial condition and results of operations.**

We have received \$4.3 million in grant funding from the Commonwealth of Australia since inception under the R&D START Program Grant Agreement, or START Program, and the Pharmaceuticals Partnerships Program Funding Agreement, or P3 Agreement. We expect we will continue to receive funding until June 2009 under the P3 Agreement. There is a risk that we will lose entitlement to the grant payments for failing to incur eligible expenditures or failing to undertake activities associated with the applicable grant or for otherwise failing to satisfy the relevant conditions in the applicable grant agreement. Furthermore, there is a risk we will not be entitled to the grants under the P3 Agreement, including, if the Commonwealth of Australia has insufficient funding for the relevant grant program, if we fail to submit reports when required, if we have not otherwise complied with our obligations under the P3 Agreement, or if the Commonwealth of Australia is entitled to or does terminate the relevant agreements. The Commonwealth of Australia may terminate the P3 Agreement under certain circumstances, including if we are in breach of the P3 Agreement, if we fail to submit reports, if there is a change of control of us, or if we become insolvent.

Under the START Program, in certain circumstances where we fail to use our best endeavors to commercialize the funded project within a reasonable time of completion of the project, or upon termination of a grant due to our breach of agreement or our insolvency, the Commonwealth of Australia may require us to repay some or all of the grants received under the program. The grants under the START Program funded certain aspects of the development of our PEP005 Gel for AK and related clinical trials. We do not expect to be required to repay the grants received under the START Program so long as we continue our efforts to commercialize the project funded by the START Program. However, if required to repay such grants, we may be required to reallocate funds needed to continue the commercialization of our products and such repayment may have an adverse effect on our cash position, business, prospects, financial condition and results of operations.



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**We will continue to need significant amounts of additional financing, which may not be available to us on favorable terms, or at all. If 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 net proceeds from the private placement completed on October 23, 2008 and interest earned thereon, together with our current cash and cash equivalents, will be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures for at least 12 months. We expect that we will need additional funds to complete the development, manufacturing, sales and marketing capabilities necessary to commercialize PEP005 Gel for AK and our other product candidates.

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:

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.

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 a \$15 million loan agreement with General Electric Capital Corporation, as agent for the lenders party thereto, on December 28, 2007. The loan agreement is guaranteed by Peplin, Inc. and each of the subsidiaries of Peplin Limited. The 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. Any future debt financing we enter into may involve similar or more onerous covenants that restrict our operations. Peplin Limited's borrowings under the loan agreement or any

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future debt financing we do will need to be repaid, which creates additional financial risk for our company, 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 agreement 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.**

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



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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,

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

Physicians typically receive reimbursement not only for the office visit relating to the treatment, but also for the cryotherapy treatment itself. We expect that physicians will only receive reimbursement for the office visit where PEP005 Gel for AK might be prescribed. 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, Australia and New Zealand. 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.

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**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 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

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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.

### **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 and filling 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 IIb and Phase III 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.

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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 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.**

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-

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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 many technologies, techniques and products for the treatment of AK, including cryotherapy with liquid nitrogen, photodynamic therapy, or PDT, which involves the in-office application of a topical solution to the AK lesion followed by the application of light therapy to activate the drug in the topical solution, and various topical agents such as Efudex, Solaraze, Carac, Fluoroplex and Aldara. The companies that are developing or marketing the topical products include Graceway Pharmaceuticals, LLC, Meda AB, iNova Pharmaceuticals (Australia) Pty Limited, Valeant Pharmaceuticals International, Dermik Laboratories, Shire plc and Bradley Pharmaceuticals, Inc. Commercial development of PDT agents is currently being pursued by a number of companies, including DUSA Pharmaceuticals, Inc., QLT Inc., Axcan Pharma Inc., Miravant, Inc., Pharmacyclics, Inc., QLT PhotoTherapeutics, Inc., medac GmbH, photonamic GmbH & Co. KG and PhotoCure ASA.

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.

### **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





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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 healthcare program 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 penalties, including civil and criminal penalties, 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.

**We may not be able to successfully integrate Neosil into our business.**

We will have to integrate the assets of Neosil with our existing operations. While we do not expect to continue the development of Neosil's products before calendar year 2009, if at all, the integration of Neosil's assets into our business will require significant efforts from both companies. We may find it difficult to integrate the assets of Neosil. Furthermore, Neosil suppliers or licensors of intellectual property may terminate their arrangements with Neosil, or demand amended terms to these arrangements. In addition, our management may have its attention diverted while trying to integrate the operations and assets of the two companies. Such diversion of management's attention or difficulties in the transition process could have an adverse impact on our business. If we are not able to integrate successfully the assets of Neosil, our future results of operations may suffer and the benefits of the merger may not be achieved.

**Changes in foreign currency exchange rates could result in fluctuations in our reported sales and earnings.**

We are exposed to foreign exchange risk, particularly with the U.S. dollar, Australian dollar and the Great 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. Although we plan to assess annually our functional currency in accordance with GAAP, our current functional currency is the Australian dollar. Because our functional currency is the Australian dollar, our reported results are subject to fluctuation resulting from changes in the Australian to U.S. 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 IIb and Phase III clinical trials for PEP005 Gel for AK and our ongoing Phase II 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.**

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.**

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.



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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.

### **Our future growth may depend on our ability to identify and acquire or in-license additional products. If we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.**

We believe that an important part of our business strategy will be to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit for our business.

We have limited resources to identify, evaluate and execute the acquisition or in-licensing of third-party products, businesses and technologies and to integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Our competitors may have stronger relationships with certain third parties with whom we are interested in collaborating or may have more established histories of developing and commercializing products. As a result, our competitors may have a competitive advantage in entering into partnering arrangements with those third parties. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

### **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, with the exception of Dr. Welburn, 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

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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.**

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.



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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;

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 ASX, subjecting us to liability, fines and lawsuits.**

The shares of our common stock are publicly traded on the Australian Securities Exchange, or the ASX, in the form of CHES 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 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 are currently taking 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.

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 of 2002 when we are required to make an assessment of our internal controls under Section 404 which is anticipated to be for fiscal 2010.

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 the measures taken to date or to be taken in the future will remediate the material weakness noted by our independent public accounting firm or 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.

The standards required for a Section 404 analysis under the Sarbanes-Oxley Act of 2002 are significantly more stringent than those for a similar analysis for non-public companies. These more stringent standards require that our audit committee be advised and regularly updated on management's review of internal controls. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company. If we are not able to timely remedy the material weakness identified in connection with our interim quarterly review, or if we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, management may not be able to assess that its internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to develop and 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. Any failure by us to timely provide the required financial information 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 Sarbanes-Oxley Act of 2002 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 of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission, 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 have no experience with the various requirements of public companies in the United States, and will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase

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our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. 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 of 2002 requires, among other things, that we maintain effective internal controls over financial reporting and disclosure controls and procedures. In particular, for the year ended 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 of 2002. 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.

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

### **Our certificate of incorporation and by-laws contain provisions that could discourage a third party from acquiring us.**

Our certificate of incorporation and by-laws contain provisions that may make the acquisition of our company more difficult without the approval of our board of directors, including, but not limited to, the following:

our board of directors is classified into three classes, each of which serves for a staggered three-year term;

only our board of directors and our chairman of the board may call special meetings of our stockholders;

we have authorized undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

our stockholders have only limited rights to amend our by-laws; and

we require advance notice for stockholder proposals.

These provisions could discourage proxy contests, make it more difficult for our stockholders to elect directors and take other corporate actions and may discourage, delay or prevent a change in control or changes in our management that a stockholder might consider favorable.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any broad range of business combinations with any stockholder who owns, or at any time in the last three years owned, 15% or more of the company's outstanding voting stock, referred to as an interested stockholder, for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

### **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.

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**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.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus includes 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:

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, including revenues expected from such 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 prospectus, the words believe, may, will, estimate, continue, anticipate, intend, expect, plan, predict, and potential 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 prospectus 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 prospectus, particularly in the section entitled 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, may cause actual results to differ materially from those contained in any forward-looking statements.

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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.

**Table of Contents****USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of Resale Securities in this offering. The selling stockholders will receive all of the proceeds from this offering.

A portion of the shares of our common stock covered by this prospectus are issuable upon exercise of warrants and the replacement options to purchase our common stock. The weighted average exercise price of the warrants issued to the selling stockholders is \$8.17 per share. The replacement exercise price of the replacement options is \$13.05 per share. Upon any exercise for cash of the warrants or options, we will receive the exercise price of the warrants or replacement options, as applicable. The warrants are also exercisable on a cashless basis. We will not receive any cash payment from the selling stockholders upon any exercise of the warrants on a cashless basis. The exercise price and number of shares of common stock issuable upon exercise of the warrants and replacement options may be adjusted in certain circumstances, including subdivisions and stock splits, stock dividends, combinations, reorganizations, reclassifications, consolidations, mergers or sales of properties and assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. To the extent we receive proceeds from the cash exercise of the warrants and replacement options, we intend to use the proceeds for the development of existing product candidates and other general corporate purposes.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all of our future earnings to finance the growth and development of our business. The payment of dividends by us on our common stock is prohibited by our loan agreement, for the term of the loan. Any future determination to pay cash dividends will be at the discretion of our board of directors, subject to consent from the lenders in accordance with the terms of our loan agreement, and will depend upon our results of operations, financial condition, current and anticipated cash needs, contractual restrictions, restrictions imposed by applicable law, operating results, capital requirements and such other factors as our board of directors deems relevant.

**PRICE RANGE OF COMMON STOCK**

Our common stock is listed on the Australian Stock Exchange in the form of CHESS Depository Interests, or 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.

	High	Low
<b>Year Ended June 30, 2007</b>		
Third Quarter	\$ 13.84	\$ 11.64
Fourth Quarter	\$ 14.79	\$ 12.47
<b>Year Ended June 30, 2008</b>		
First Quarter	\$ 16.95	\$ 12.71
Second Quarter	\$ 16.92	\$ 12.65
Third Quarter	\$ 15.59	\$ 9.06
Fourth Quarter	\$ 10.19	\$ 6.98
<b>Year Ended June 30, 2009</b>		
First Quarter	\$ 9.78	\$ 5.51
Second Quarter (through November 24, 2008)	\$ 6.35	\$ 3.79

The last reported sales price of our CDIs on the ASX on November 24, 2008 was A\$0.28 per share. There were approximately 106 holders of record of our common stock as of November 24, 2008.

**Table of Contents****SELECTED FINANCIAL DATA**

We derived the consolidated statements of operations data presented below for each of the three years ended June 30, 2006, 2007 and 2008, and the consolidated balance sheet as of June 30, 2007 and 2008, from our audited consolidated financial statements included elsewhere in this prospectus. We derived the consolidated statements of operations data for the three months ended September 30, 2007 and 2008 and for the period from inception to September 30, 2008 and the consolidated balance sheet data as of September 30, 2008 from our unaudited consolidated financial statements included elsewhere in this prospectus. We derived the consolidated statement of operations data for each of the two years ended June 30, 2004 and 2005, and consolidated balance sheet data as of June 30, 2004, 2005 and 2006 from our audited consolidated financial statements not included in this prospectus. Interim financial results are not necessarily indicative of results that may be expected for the full fiscal year. The unaudited financial statements have been prepared on a basis consistent with the audited financial statements. 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 prospectus.

	Year Ended June 30,					Three Months Ended September 30,		Period from Inception to September 30,
	2004	2005	2006	2007	2008	2007 (Unaudited)	2008 (Unaudited)	2008 (Unaudited)
(Amounts in thousands, except for per share amounts)								
<b>Consolidated Statements of Operations Data:</b>								
Revenues	\$ 121	\$ 5,610	\$	\$	\$	\$	\$	\$ 5,771
Cost of operations:								
Research and development	5,624	7,163	9,178	17,751	19,579	4,137	6,127	71,984
Sales, general and administrative	1,501	1,657	2,070	4,112	8,089	1,359	3,953	23,813
Loss from operations	(7,004)	(3,210)	(11,335)	(22,350)	(27,668)	(5,496)	(10,080)	(90,026)
Other income (expenses)	1,084	472	995	1,787	1,733	933	(121)	7,783
Net loss before income taxes	(5,920)	(2,738)	(10,340)	(20,563)	(25,935)	(4,563)	(10,201)	(82,243)
Income tax expense					(21)		(2)	(22)
Net loss	\$ (5,920)	\$ (2,738)	\$ (10,340)	\$ (20,563)	\$ (25,956)	\$ (4,563)	\$ (10,203)	\$ (82,265)
<b>Net loss per share(1):</b>								
Basic and diluted	\$ (1.60)	\$ (0.62)	\$ (1.74)	\$ (2.31)	\$ (2.57)	\$ (0.49)	\$ (0.99)	
<b>Shares used to compute net loss per share(1):</b>								
Basic and diluted	3,702	4,388	5,946	8,902	10,097	9,388	10,341	

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



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	As of June 30,					For Period
	2004	2005	2006	2007	2008	Ended September 30, 2008 (unaudited)
	(Amount in thousands)					
<b>Consolidated Balance Sheet Data:</b>						
Cash and cash equivalents	\$ 5,286	\$ 6,244	\$ 16,840	\$ 20,246	\$ 25,231	\$ 12,823
Working capital	998	5,102	14,781	17,211	21,530	9,195
Total assets	6,785	7,777	25,314	24,088	35,969	21,961
Non-current liabilities			62	102	9,336	7,969
Stockholders' equity	1,579	6,506	16,385	19,737	16,215	4,437

**Table of Contents****MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion of our financial condition and results of operations should be read in conjunction with Selected Financial Data and our consolidated financial statements and related notes included elsewhere in this prospectus. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of events may differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under Risk Factors and elsewhere in this prospectus. We do not have any intention or obligation to update forward-looking statements in this prospectus after the date of this prospectus, except as required by law.*

**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, which is the first in a new class of compounds and is 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 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, for which we recently commenced a Phase III clinical trial, 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.

We are also developing a product candidate containing PEP005 for the treatment of superficial basal cell carcinoma, or superficial BCC. This product candidate is currently in Phase IIa clinical trials 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.

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 and back. We expect this program will require at least two pivotal Phase III clinical trials comprising one Phase III clinical trial for non-head applications and one Phase III clinical trial for head applications, in each case together with supportive safety and other studies. After completing our PEP005-006 Phase IIb clinical trial, we submitted the results of the trial to the FDA and, upon review, the FDA stated that the trial was an adequate dose ranging trial of PEP005 Gel for AK in non-facial treatment locations. Subsequently, we submitted a request for a Special Protocol Assessment, or SPA, with the FDA for our initial Phase III clinical trial for non-head applications. In the SPA process, the FDA reviews the design, size and planned analysis of a Phase III 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 III 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 called this Phase III clinical trial for non-head applications our REGION I clinical trial. We commenced the REGION I clinical trial in September 2008. We initiated a Phase IIb dose ranging clinical trial for head applications of PEP005 Gel for AK in June 2008. This Phase IIb clinical trial is intended to support the design of our subsequent Phase III clinical trial for head applications, which we plan to initiate in 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 2010, assuming a successful end-of-Phase II meeting with the FDA and the successful completion of our Phase III clinical program.

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We operate our manufacturing facility for the drying, milling, extraction and purification of PEP005 in Southport, Queensland, Australia. Other activities relating to manufacturing are undertaken by various outside contractors. Currently, formulation, filling and packaging of our AK product candidates is undertaken by a single third-party in San Antonio, Texas. The clinical supplies are then shipped to locations designated by us or our clinical research organization for use in trials. Batches used in some pre-clinical activities are manufactured, packaged and labeled by a single third-party in the United Kingdom. We believe we will need to increase our manufacturing capacity if any of our product candidates are approved for commercialization.

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 September 30, 2008, we had an accumulated deficit of \$82.3 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 preclinical studies, clinical trials, research and development, manufacturing development and regulatory approvals. We do not expect to generate revenue from the sale of our products until one or more of our product candidates is approved for sale by the FDA, which we do not expect to occur prior to 2010. 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.

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 consisted solely of the business and operations of Peplin Limited.

### **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 prospectus and the accompanying financial information to a fiscal year end for each year of 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 related to development costs. 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.



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

In fiscal 2008, we reversed \$1.1 million of previously accrued research and development expense based upon a change to the total clinical trial cost estimate provided by our contract research organization who assisted in the planning, oversight and monitoring of the clinical trial. This has been treated as a change in estimate in the consolidated financial statements.

### ***Revenue Recognition***

We apply the revenue recognition criteria outlined in Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition* and Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. In applying these revenue recognition criteria, we consider a variety of factors in determining the appropriate method of revenue recognition under our 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.

### ***Government Grant Income***

Government grants, which support our research efforts in specific projects, 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.

In 2006, we were awarded a research grant under the Australian Government's Pharmaceuticals Partnerships Program, or P3 program. Under the terms of the P3 program, we received 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. There are no unfulfilled conditions or contingencies attaching to this grant nor are there any repayment provisions.

### ***Stock-Based Compensation***

We account 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)*, or SFAS No. 123R. We have adopted SFAS No. 123R and applied the measurement and valuation provisions to all stock options granted since our inception. Stock based compensation cost 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. We use the simplified method to estimate expected life as we do not have sufficient historical exercise history. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results differ from our 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 cost for stock options granted to non-employees is measured at the earlier of the date at which the commitment for performance by the consultant or non-employee to earn the equity instrument is reached or the date at which the consultant's or non-employee's performance is complete. The fair value of stock options as calculated using a Black Scholes valuation model and are expensed over the performance period and are subject to remeasurement over their vesting terms.

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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, we have utilized an average volatility based on guideline companies within the biotechnology sector as there was insufficient company trading history to determine an accurate volatility rate. For options issued subsequent to June 30, 2006, through to the date of the Reorganization, we calculated expected volatility based on our own trading activity data. Upon the Reorganization, primarily due to our underlying security changing from an Australian ordinary share to U.S. common stock, we began to use U.S. risk-free interest rates and volatilities based on NASDAQ-listed peer companies within the biotechnology sector.

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### ***Income Tax***

We account for income taxes under the provisions of SFAS No. 109, *Accounting for Income Taxes*, or SFAS No. 109. SFAS No. 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 income statement in the period that it 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 be not realized.

We adopted the provisions of FASB interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, or FIN 48. 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 September 30, 2008, 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. 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. We also incur significant expenses to operate our clinical trials including 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. 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 general and administrative expenses include facility costs not otherwise included in research and development expenses, patent related costs and professional fees for legal, consulting and accounting services.

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### ***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 its P3 program. Our most recent R&D START grant 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 inception to September 30, 2008 was \$2.2 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 with General Electric Capital Corporation.

### ***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.

As of June 30, 2008, we had net operating loss carry-forwards of \$31.1 million. The majority of these net operating loss and tax credit carryforwards were incurred in Australia and will carry forward subject to the satisfaction of either a continuity of ownership or business test as applied in that country. Utilization of net operating loss carryforwards may be subject to annual limitation due to Australian Tax Office requirements that are applicable if we experience an ownership change that may occur, for example, as a result of this offering aggregated with certain other sales of our stock before or after this offering. Due to our 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***

Our functional currency for accounting purposes is the Australian dollar. However, our reporting currency is the U.S. dollar. As a result, in preparing our financial statements for purposes of this prospectus, and going forward in our annual and quarterly reports, we must convert the amounts recorded in our functional currency to our reporting currency. For revenues and expenses reported during any period, we use the average foreign currency exchange rate during that period. For assets and liabilities, we use the foreign currency exchange rate as of the end of such period. Given the fluctuations in foreign currency exchange rates, we may experience changes in reported amounts from period to period that occur primarily as a result of these fluctuations and that are not reflective of actual changes in our business or operations.

### ***Comparison of Three Months Ended September 30, 2007 and 2008***

*Revenue.* We recorded no revenue for the three months ended September 30, 2007 and 2008.

*Research and Development Expenses.* Research and development expenses increased 68% from \$3.7 million in the three months ended September 30, 2007 to \$6.1 million in the three months ended September 30, 2008. The increase in the three months ended September 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. We expect research and development expenses to continue to increase as we devote substantial resources to research and development to support the continued development of our product candidates, including the commencement of our Phase III clinical trial program for PEP005 Topical for AK, which includes a Phase IIb clinical trial.

Research and development expenses represented 66% of total operating expenses for the three months ended September 30, 2007 and 61% for the three months ended September 30, 2008.

We announced commencement of our Phase III clinical trial for non-head applications of PEP005 Topical for AK in September 2008.



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*Sales, General and Administrative Expenses.* Sales, general and administrative expenses increased 191% from \$1.4 million in the three months ended September 30, 2007 to \$4.0 million in the three months ended September 30, 2008. We have expanded our legal, commercial and accounting staff, added infrastructure and incurred additional costs in preparation for operating as a U.S. public company, including directors and officers insurance, investor relations programs, increased director fees and increased professional fees. Due to the focus on core products and expanded timelines, there has been a small decrease in professional and consulting fees. We expect this to increase in the future as the commercial, sales and marketing functions become more of a focus for the Company.

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 \$0.9 million for the three months ended September 30, 2007 and \$(0.1) million for the three months ended September 30, 2008. We received \$0.7 million and \$0.2 million related to government grants during the three months ended September 30, 2007 and 2008, respectively. We also incurred \$(0.6) million in interest expense in 2008 on our loan from GE which did not exist at September 30, 2007.

***Comparison of Years Ended June 30, 2007 and 2008***

*Revenue.* We recorded no revenue for the years ended June 30, 2007 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 III 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 IIB clinical trial of PEP005 Gel for AK and Phase II clinical trial for PEP005 Gel for BCC. We also intend to expand our research and development efforts and to expand our manufacturing development. We do not expect to commence our Phase III clinical program for PEP005 Gel for BCC before calendar 2010.

*Sales, General and Administrative Expenses.* Sales, 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 (expense) 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.

***Comparison of Years Ended June 30, 2006 and 2007***

*Revenue.* We recorded no revenue for the years ended June 30, 2006 and 2007.

*Research and Development Expenses.* Research and development expenses increased 97% from \$9.3 million in the year ended June 30, 2006 to \$18.2 million in the year ended June 30, 2007. The increase in the year ended June 30, 2007 was due primarily to the commencement of our PEP005-006 and PEP005-007 Phase II clinical trials, which resulted in increased costs of \$4.8 million, increased spending of approximately \$3.6 million on preclinical studies, clinical trials and additional internal research efforts and increased staffing and other personnel related costs, and approximately \$0.6 million in non-cash stock-based compensation. Research and development expenses represented 82% of total operating expenses for each of the years ended June 30, 2006 and 2007.



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*Sales, General and Administrative Expenses.* Sales, general and administrative expenses increased 99% from \$2.1 million in the year ended June 30, 2006 to \$4.1 million in the year ended June 30, 2007. This increase was primarily due to increased staffing necessary to manage and support our growth, particularly in connection with establishing our U.S. office, as well as approximately \$0.8 million in non-cash stock-based compensation in the year ended June 30, 2007.

*Other Income (Expense).* We had total other income of \$1.0 million for the year ended June 30, 2006 and \$1.8 million for the year ended June 30, 2007. This increase was primarily due to increased average cash balances in 2006 due to our raising of approximately \$27.8 million in net proceeds from the sale of our ordinary shares to various investors in mid and late calendar year 2006. We recognized \$0.4 million and \$0.2 million related to government grants during the years ended June 30, 2006 and 2007, respectively.

## **Liquidity and Capital Resources**

Since inception through September 30, 2008, we have financed our operations primarily through placements of equity securities, receiving aggregate net proceeds from such placements totaling \$75.6 million, the entrance by Peplin Limited, our wholly-owned subsidiary, into a \$15.0 million loan agreement and income primarily from Allergan totaling \$5.8 million and from Australian Government grants totaling \$4.5 million. As of September 30, 2008, we had \$12.8 million in cash and cash equivalents. Our cash and cash equivalents are held in a variety of interest bearing instruments, including money market accounts with high credit rated Australian banks. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation.

Net cash used in operating activities was \$8.8 million, \$18.3 million, \$25.8 million, and \$10.1 million in the years ended June 30, 2006, 2007 and 2008 and the three months ended September 30, 2008, respectively. The net cash used in each of these periods primarily reflects net loss for these periods, offset in part by depreciation, non-cash stock-based compensation and non-cash changes in operating assets and liabilities.

Net cash used in investing activities was \$1.1 million, \$0.7 million, \$0.8 million, and \$0.1 million in the years ended June 30, 2006, 2007 and 2008 and the three months ended September 30, 2008, respectively. Investing activities consist primarily of purchases and sales of short-term deposits and plant and equipment purchases. We expect to continue to make investments in the purchase of property and equipment to support our expanding operations.

Net cash provided by financing activities was \$20.5 million, \$18.8 million, \$28.8 million, and \$(1.6) million in the years ended June 30, 2006, 2007 and 2008 and the three months ended September 30, 2008, respectively. Financing activities consist primarily of proceeds from the sale of our shares, as well as movements in our restricted cash balances and, in the year ended June 30, 2008, the entrance by Peplin Limited, our wholly-owned subsidiary, into a \$15 million loan agreement.

On September 11, 2007 and October 8, 2007, Peplin Limited issued an aggregate of 22,222,222 ordinary shares, or 1,111,112 shares of common stock after giving effect to the Reorganization, to certain investors that entered into subscription agreements with Peplin Limited on August 9, 2007. The ordinary shares were issued for an aggregate consideration of approximately \$17.1 million. In addition, Peplin Limited reimbursed MPM BioVentures IV LLC for \$14,700 of its legal costs incurred in connection with the transaction. For a more complete description of this transaction, see Certain Relationships and Related Party Transactions-Sales of Securities.

On December 28, 2007, Peplin Limited, our wholly-owned subsidiary, entered into a \$15.0 million loan agreement with General Electric Capital Corporation, as agent for the lenders party thereto. As of that date, we have paid to General Electric Capital Corporation non-refundable fees and interest totaling \$337,500. The loan agreement is guaranteed by Peplin, Inc. and each of the subsidiaries of Peplin Limited. The loan agreement fully amortizes over

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a series of thirty-six monthly payments. Under the 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 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 the 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 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 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 September 30, 2008, we were in compliance with all covenants. In addition, in consideration for this financing, we granted GE Capital Equity Investments, Inc. and Oxford Finance Corporation 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. This prospectus forms part of a registration statement that registers the resale of the underlying common stock.

Effective October 16, 2008, we acquired all the outstanding shares of Neosil, Inc., Neosil, a privately held, dermatology-focused company in an all stock transaction. The purchase price of \$6.7 million, which was based on the minimum cash balance required to be in Neosil at the closing was paid with 819,378 shares of common stock.

On October 23, 2008, we issued 3,980,259 shares of our common stock at \$6.05, and warrants to purchase 1,326,753 shares of our common stock, to raise \$24,067,380 cash. As part of the agreement, for each three shares of common stock acquired, investors received a warrant to purchase one share of our common stock. The agreement was approved by our stockholders on October 6, 2008. We incurred total transactions costs of \$3,019,782.

We believe that our current cash and cash equivalents, will be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. 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. 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. Our future funding requirements will depend on many factors, including:

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

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

We may need to raise additional funds to support our operations, and 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

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continue development of our product candidates or we could 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 our loan agreement. 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, 2008 were as follows:

Contractual Obligations	Total	Payments Due By Period			More than 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
		(In thousands)			
Long-term debt obligations(1)	\$ 13,776	\$ 5,163	\$ 8,613	\$	\$
Research and development expenditure(2)	8,692	7,982	710		
Operating lease obligations	1,830	581	1,222	27	
Interest obligations on long-term debt	1,564	973	591		
General and administration	169	169			
Total	\$ 26,031	\$ 14,868	\$ 11,136	\$ 27	\$

- (1) In December 2007, Peplin Limited, our wholly-owned subsidiary, entered into a \$15 million loan agreement with General Electric Capital Corporation, as agent for the lenders party thereto.
- (2) Represents commitments under clinical trial agreements, preclinical research studies and development obligations.

As of September 30, 2008, there were no material changes to our contractual obligations set forth above.

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 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.

**Related Party Transactions**

For a description of our related party transactions, see the section of this prospectus entitled Certain Relationships and Related Party Transactions.

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### **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.

### **Quantitative and Qualitative Disclosure About Market Risk**

Our exposure to market risk is confined to our cash and cash equivalents, which 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 September 30, 2008, we had cash and cash equivalents of \$12.8 million. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any negative impact on the realized value of our cash equivalents.

Currently, we are exposed to foreign exchange risk, particularly with the U.S. dollar, Australian dollar and the Great 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 a U.S. dollar, Australian dollar and Great British pound bank accounts and deposits to primarily facilitate the payment of research and development activities. In addition we attempt to denominate contracts in Australian dollars whenever possible, regardless of the country in which work will be performed. Because our functional currency is the Australian dollar, our reported financial results are subject to fluctuation resulting from changes in the Australian to U.S. exchange rate.

### **Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

Our management, including the Chief Executive Officer and Chief Financial Officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report pursuant to Exchange Act Rule 13a-15(b). On October 31, 2008, we filed certain financial information with the Australian Securities Exchange, or the ASX, as required by the listing standards of the ASX. We inadvertently failed to file a Current Report on Form 8-K containing that information in a timely manner. Based solely on that occurrence, the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of the period covered by this report were not effective to ensure that information required to be disclosed by the Company in current reports filed with the Securities and Exchange Commission is reported within the required time periods. We are implementing additional disclosure controls and procedures that are designed to address the timely filings of current reports in future periods.

#### ***Changes in Internal Control Over Financial Reporting***

In connection with our September 30, 2008 quarterly financial statement filing, we, together with our independent registered public accounting firm, identified a material weakness in our internal control over our period end close process and specifically the accrual processes. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. 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 the Sarbanes-Oxley Act. Had we and our internal 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 for the three month period ended September 30, 2008. We are currently taking steps to remediate the material weakness including engaging our independent registered public accounting firm to review and test our current internal controls and provide recommendations for improvements to our current internal controls processes, providing additional training to existing personnel and improving internal review processes regarding accruals and the period end close process.

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We are not yet required to comply with Section 404 of the Sarbanes-Oxley Act of 2002 due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. At the end of the fiscal year ending June 30, 2010, Section 404 will require our management to provide an assessment of the effectiveness of our internal control over financial reporting, and our independent registered public accounting firm will be required to report on the effectiveness of internal control over financial reporting. We are in the process of performing the information system and process documentation, and evaluation and testing required for management to make this assessment and for our independent registered public accounting firm to provide their attestation report. We have not completed this process or the assessment, and this process will require significant amounts of management time and resources. In the course of evaluation and testing, management may identify deficiencies that will need to be addressed and remediated.



**Table of Contents****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, which is the first in a new class of compounds and is 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 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, for which we recently commenced a Phase III clinical trial, 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.

We are also developing a product candidate containing PEP005 for the treatment of superficial basal cell carcinoma, or superficial BCC. This product candidate is currently in Phase IIa clinical trials 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.

In pursuit of U.S. Food and Drug Administration, or FDA, approval, we recently completed a Phase IIb clinical trial designed to evaluate the safety, tolerability and efficacy of three different dosages of PEP005 Gel for AK when used as a field-directed therapy for the treatment of non-facial AK lesions, including lesions on the scalp. Field-directed therapy refers to the application of PEP005 Gel for AK to a broad area of sun damaged skin that includes AK lesions. We believe that the results of this trial, which we call PEP005-006, suggest that a single application of PEP005 Gel for AK, each day, for two or three consecutive days, presents a favorable safety profile and is well tolerated. Furthermore, the trial demonstrated a statistically significant and clinically meaningful lesion clearance by all measures evaluated and at all doses studied. The results also demonstrated a clear dose-response relationship between activity of the drug and dosage for all treatment groups. In addition, we recently completed a Phase IIa clinical trial designed to determine the optimal tolerated regimen and safety of PEP005 Gel for AK as a field-directed therapy for treatment locations on the face. We believe that the results of this trial, which we call PEP005-007, suggest that each dose of PEP005 Gel for AK studied at and below the maximum tolerated dose, or MTD, presents a favorable safety profile and is well tolerated. Furthermore, we are currently evaluating PEP005 Gel for BCC when used as a tumor-directed therapy in a Phase IIa clinical trial which we call PEP005-009.

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 and back. We expect this program will require at least two pivotal Phase III clinical trials comprising one Phase III clinical trial for non-head applications and one Phase III clinical trial for head applications, in each case together with supportive safety and other studies. After completing our PEP005-006 Phase IIb clinical trial, we submitted the results of the trial to the FDA and, upon review, the FDA stated that the trial was an adequate dose ranging trial of PEP005 Gel for AK in non-head treatment locations. Subsequently, we submitted a request for a Special Protocol Assessment, or SPA, with the FDA for our initial Phase III clinical trial for non-head applications. In the SPA process, the FDA reviews the design, size and planned analysis of a Phase III 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 III 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 called this Phase III clinical trial for non-head applications our REGION I clinical trial. We commenced the REGION I

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clinical trial in September 2008. We initiated a Phase IIb dose ranging clinical trial for head applications of PEP005 Gel for AK in June 2008. This Phase IIb clinical trial is intended to support the design of our subsequent Phase III clinical trial for head applications, which we plan to initiate in 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 2010, assuming a successful end-of-Phase II meeting with the FDA and the successful completion of our Phase III clinical program.

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. 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.

### **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 range from surgical or ablative procedures, where lesions or tumors are destroyed or cut out of the skin, to topical treatments that are designed to clear the lesion or tumor through repeated application, to 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.

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*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. 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. In published clinical studies for one type of PDT, marketed as Levulan Kerastick, PDT has demonstrated complete clearance of all treated AK lesions in 66% of patients, eight weeks after initial treatment. Following a second treatment, 85% of patients had complete clearance. 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 and the surrounding sun-damaged skin where 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 during treatment. Following the treatment, a period of healing is generally required. In superficial BCC applications, topical imiquimod is applied by the patient five times per week for six weeks.

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*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 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. 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 at 30 days post-treatment, or 60 to 120 days after initial treatment, in 18% to 47% of patients, based on the location of the lesion. 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 treatments for AK lesions, and in combination with pharmacotherapy in approximately 9% of the treatments. Topical drugs are used alone in approximately 16% of AK treatments. 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;

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 a new class of 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

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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. We refer to our lead compound derived from *E. peplus* as PEP005 (ingenol mebutate), or PEP005.

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 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***

We recently completed our PEP005-006 Phase IIb clinical trial of PEP005 Gel for AK as a field-directed therapy for non-facial AK lesions, including lesions on the scalp. Results from the trial of 222 patients suggest that the drug presents a favorable safety profile and is well tolerated at all tested doses. The trial involved a single application of either 0.025% or 0.05% of PEP005 gel each day, for two or three consecutive days. The most common side effects were local skin responses, such as redness, flaking or scaling and crusting. Local skin responses typically resolved in two to four weeks after completion of treatment. The trial evaluated three efficacy measures using various lesion clearance metrics. On the primary efficacy measure, the partial AK clearance rate, 75% of the patients in the highest dose group cleared three quarters or more of their lesions 57 days post-treatment and 56% of patients in the lowest dose group cleared three quarters or more of their lesions 57 days post-treatment. The two secondary efficacy measures were the complete AK clearance and the baseline AK clearance rate. In the highest dose group the complete AK clearance rate and baseline AK clearance rate were 54% and 58% of patients, respectively, and in the lowest dose group were 40% and 42% of patients, respectively. All of these clearance results were statistically significant when compared with the vehicle gel.

We also recently completed our PEP005-007 Phase IIa clinical trial of PEP005 Gel for AK as a field-directed therapy for AK in treatment locations on the face. This trial of 86 patients examined concentrations from 0.0025% to 0.025% PEP005 Gel for AK for two and three consecutive day dosing regimens. We believe that the results from this trial suggest that each dose of PEP005 Gel for AK studied at and below the MTD presents a favorable safety profile and is well tolerated. Based on these results, we plan to conduct a Phase IIb clinical trial to further study a range of doses from 0.005% to 0.015% PEP005 Gel for AK, applied daily for two or three consecutive days for further development in the treatment of AK lesions on head locations.

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;
- 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***

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The preliminary results from our recent PEP005-003 Phase IIa 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

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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 II dose escalation clinical trial, which we call PEP005-009, in which we are increasing the dosage of PEP005 Gel for BCC to establish the 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 III clinical program for PEP005 Gel for BCC until 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 short coming 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.

While we believe PEP005 Gel for AK and PEP005 Gel for BCC offer advantages to other currently existing treatment options for AK or BCC, the potential side effects of these product candidates include redness, flaking or scaling, crusting, swelling, blistering, and ulceration. The side effects from these product candidates may last as long as four weeks or more. Moreover, patients may believe that treatment with products containing PEP005 will be uncomfortable or inconvenient. Physicians and patients may perceive that the side effects of our products outweigh the benefits of their use and, as result, may be unwilling to change their current treatment regimens. Furthermore, even if approved by the FDA, physicians may not prescribe our products until we do have long term data regarding their safety and efficacy.

### **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 or three tubes and be sufficient for a course of treatment of a 25 cm<sup>2</sup> area, which, for example, approximates half the sun damaged area to be treated on the typical forehead or cheek. We have selected our optimal treatment course and concentration for non-head treatment areas and are currently defining an optimized concentration of the drug in which the course of therapy is once a day application for two or three consecutive days for head treatment areas.

*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 six clinical trials in our AK program with a total of 329 patients treated with active drug, including our recent Phase IIb clinical trial of 222 patients with non-facial field treatment, which we refer to as our PEP005-006 trial, that included 162 patients on active drug and our most recent Phase IIa clinical trial of 86 patients treated on the face, which we refer to as our PEP005-007 trial, in which all patients were on 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 for both facial and non-facial AK lesions to its evaluation as a field-directed therapy for non-facial and facial AK lesions. 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. Based on correspondence with the FDA and guidelines recognized by the FDA, we expect that a carcinogenicity study for PEP005 Gel for AK will not be required to support our NDA filing given the relatively short two or three day treatment regimen of the drug.

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 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 and each patient's global response to treatment, which includes both skin responses to treatment and other physical responses. 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. Finally, we evaluate a patient's global response to treatment based on a subjective evaluation made by the investigator using a scale of none, mild, moderate and severe. A severe global response rating indicates that a patient was highly responsive to the treatment, but does not necessarily indicate the occurrence of an adverse event.

We evaluated clearance rates in our PEP005-006 and PEP005-007 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 57<sup>th</sup> day post-treatment, manifested 75% or greater reduction in the number of AK lesions identified at baseline in the treatment area. Lesions that were not present at the baseline measurement but that manifest during the course of treatment are not counted under this metric.

*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.

*Baseline AK lesion clearance rate.* This rate is defined as the proportion of patients in the trial who, on the 57th day post-treatment, manifested 100% reduction in the number of AK lesions identified at baseline in the treatment area. Lesions that were not present at the baseline measurement but that manifest during the course of treatment are not counted under this metric.

*PEP005-006 Clinical Trial.* Our PEP005-006 Phase IIb clinical trial was a multi-center, randomized, double-blind, double-dummy, vehicle-controlled trial, designed to assess safety, tolerability and efficacy of PEP005 Gel for AK as a field-directed therapy in non-facial treatment locations. The trial treated 222 patients, 178 male and 44 female, with a mean age of 67 years. Patients were randomized into one of four treatment groups:

50 patients that received a concentration of 0.025% administered days one, two and three;

55 patients that received the vehicle gel on day one and a concentration of 0.05% on days two and three;

57 patients that received a concentration of 0.05% on days one, two and three; and

60 patients that received the vehicle gel on days one, two and three.

A vehicle-controlled study compares the result of a pharmaceutical product against its vehicle, which is the portion of the product that does not contain the active pharmaceutical ingredient. Either the vehicle or study medication in the PEP005-006 trial was applied to a 25 cm<sup>2</sup> area of skin containing four to eight AK lesions on the arm, shoulder, chest, back or scalp. Patients applied the treatment themselves, with at least the initial treatment occurring under physician supervision. Our vehicle was an isopropyl alcohol based gel. We believe our vehicle reaction is consistent with that observed in other dermatologic trials of AK.

*Safety and Tolerability.* At all doses, PEP005 Gel for AK suggested a favorable safety profile and was well tolerated by the patients in the trial. Across all active treatment groups, 24 patients of a total 159, were reported not eligible to apply the third day dose due to response to the drug, the majority of which received the highest concentration of the drug. There were no drug related serious adverse events reported. The most common side-effects were localized skin responses at the treatment site, compromising redness, flaking or scaling and crusting. Prior to



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treatment and at each of the assessment dates, investigators evaluated each of the localized skin responses on a scale designed to measure the intensity of the localized skin response. The scores for each localized skin response were added to create a composite localized skin response score for each patient. The average composite

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localized skin response score increased significantly on days two and three from the pre-treatment score, but had generally declined to approximately the pre-treatment score by day 29. No patients discontinued the trial due to adverse events. Investigators in the trial reported that the majority of patient global responses to treatment were either mild or moderate, with approximately 19% of patients in the highest dosage treatment group experiencing a severe response.

**Efficacy.** Efficacy was evaluated 57 days post-treatment using a modified intent to treat patient population, which consisted of all patients that received at least one dose and had at least one assessment following the baseline assessment. 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.

Efficacy measure	Vehicle	0.025% (3 Days)		0.05% (2 Days)		0.05% (3 Days)	
		%	p-value	%	p-value	%	p-value
Partial clearance rate	22%	56%	0.0002	62%	<0.0001	75%	<0.0001
Complete AK lesion clearance rate	12%	40%	0.0006	44%	0.0001	54%	<0.0001
Baseline AK lesion clearance rate	13%	42%	0.0007	44%	0.0003	58%	<0.0001

**Subjective Assessment.** As part of the assessment, patients were asked to evaluate the convenience and ease of use of the treatment, cosmetic outcome of the treatment, their satisfaction with the treatment compared to prior AK treatments and their overall level of satisfaction. Patients ranked their response on a scale from 1, very negative, to 7, very positive, with 4 being neutral. At the highest dose group, the average patient score measuring satisfaction in comparison with prior AK treatments was 5.7, and at the lowest dose group was 5.5. The average patient score for overall satisfaction at the highest dose group was 6.0, and at the lowest dose group was 6.1.

**PEP005-007 Clinical Trial.** Our PEP005-007 Phase IIa clinical trial was a multi-center, open label study designed to determine the optimal tolerated regimen and safety of PEP005 Gel for AK when applied on the face, which included contiguous areas of the face and scalp. Treatment with PEP005 Gel for AK was evaluated at concentrations from 0.0025% to 0.025% PEP005 Gel for AK administered daily by the patient for two or three consecutive days. Medication was applied to a 25 cm<sup>2</sup> contiguous area of skin containing four to eight AK lesions. The study's primary objective was to determine the optimal tolerated regimen of PEP005 Gel for AK, when administered as either two consecutive day or three consecutive day application schedules. The study's secondary objective was to evaluate efficacy based on the complete clearance rate, partial clearance rate and baseline clearance rate of AK lesions on the 57<sup>th</sup> day.

A total of 94 patients were screened into the study, with 88 patients meeting the eligibility criteria and subsequently scheduled for treatment with PEP005 Gel for AK. Eighty-six patients completed the study. All patients enrolled in this study were Caucasian. Based on the results from PEP005-007, we have established the MTD at 0.025% PEP005 Gel for AK applied daily for two consecutive days as a field-directed therapy on the face.

**Safety and Tolerability.** At all dosages studied at and below the MTD, PEP005 Gel for AK suggested a favorable safety profile and was well tolerated by patients. There were no reports of serious adverse events related to study medication. The most common side effects were localized skin responses including redness, flaking or scaling, crusting, vesicles and swelling in the treatment area. Prior to treatment and at each of the assessment dates, investigators evaluated each of the localized skin responses on a scale designed to measure the intensity of the localized skin response. The scores for each localized skin response were added to create a composite localized skin response score for each patient. The average composite localized skin response score increased significantly on days two and three from the pre-treatment score, but had generally declined to approximately the pre-treatment score by day 29. Investigators in the trial reported that the majority of patient global responses to treatment were either mild or moderate across all treatment groups.

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**Efficacy.** Given the small number of patients in each treatment group, the trial was not designed to generate, nor did it generate, meaningful efficacy data and a clear dose response was not apparent from any of the three efficacy measures. Complete clearance rates ranged from 38% to 100% in the various dosage groups, excluding the lowest which had 0%, and partial clearance rates ranged from 63% to 100% in the various dosage groups, excluding the lowest which had 25%.

**Subjective Assessments.** The study collected a subjective impression of treatment as reported by patients (although only for patients who were scheduled to receive three days dosing). As part of the assessment, patients were asked to evaluate the convenience and ease of use of the treatment, healing time, cosmetic outcome of the treatment, their satisfaction with the treatment compared to prior AK treatments and their overall level of satisfaction. Patients ranked their response on a scale from 1, very negative, to 7, very positive, with 4 being neutral. At the highest dose group, the average and median patient score measuring overall satisfaction was 6.5 and 7.0, respectively, and at the lowest dose group the average and median patient score measuring overall satisfaction was 6.4 and 7.0, respectively.

**AK Clinical Development Plan.** We believe the clinical data from our recently completed PEP005-006 and PEP005-007 Phase II clinical trials in AK patients has allowed us to define the appropriate concentration and treatment regimen for non-head field-directed therapy and has narrowed the appropriate treatment regimen and range of concentrations to study for head field-directed therapy. In addition, based on the results from our PEP005-006 trial, we determined that the scalp responds to the application of PEP005 Gel for AK more like areas on the face, and as a result, we include the scalp with the face which comprise our head trials going forward.

**Non-head Phase III clinical trial.** After completing our PEP005-006 Phase IIb clinical trial, we submitted the results of the trial to the FDA and, upon review, the FDA stated that the trial was an adequate dose ranging trial for applications of PEP005 Gel for AK in non-head treatment locations. Subsequently, we submitted a request for a Special Protocol Assessment, or SPA, to the FDA for our initial Phase III clinical trial for non-head applications. We refer to this Phase III clinical trial for non-head applications as our REGION I clinical trial. In the SPA process, the FDA reviews the design, size and planned analysis of a Phase III 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. Our REGION I clinical trial is a multi-center, randomized, double blind, vehicle controlled clinical trial designed to evaluate the efficacy of 0.05% PEP005 Gel for AK compared to a vehicle in patients with AK lesions on non-head locations. We expect to enroll approximately 250 patients who would apply the study medication or vehicle gel at home once a day for two consecutive days to a 25 cm<sup>2</sup> treatment area containing four to eight AK lesions. The primary efficacy endpoint for this clinical trial will be the complete clearance rate of AK lesions and the secondary efficacy endpoint will be the partial clearance rate of AK lesions. We plan to evaluate efficacy on the 57th day after treatment. The FDA has indicated its agreement with the design, clinical endpoints and planned statistical analysis of our REGION I 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. If the trial is successful in meeting its predetermined objectives, we will be able to rely on the trial in support of the efficacy claims in our NDA for PEP005 Gel for AK. We commenced our REGION I clinical trial in September 2008.

**Head Phase IIb and Phase III clinical trials.** Prior to initiating a Phase III clinical trial for head applications, we are conducting a dose ranging Phase IIb clinical trial for head applications, which we initiated in June 2008. This trial is a multi-center, randomized, double blind, vehicle controlled clinical trial to evaluate the safety and efficacy of each of 0.005%, 0.010% or 0.015% PEP005 Gel for AK. Patients participating in this trial are randomized into two treatment arms, utilizing either a two day or three day treatment regimen. Patients in each treatment arm apply either one of the active concentrations of PEP005 Gel for AK or vehicle gel to AK lesions on head locations. We have completed enrollment in this trial and expect to announce preliminary results during the first quarter of 2009. Patients in this trial who apply the study medication or vehicle gel at home once a day for two or three consecutive days to a 25 cm<sup>2</sup> treatment area containing four to eight AK lesions. The primary efficacy endpoint for this clinical trial is the complete clearance rate of AK lesions and the secondary efficacy endpoint is the partial clearance rate of AK lesions. We plan to evaluate efficacy on the 57th day after treatment. This Phase IIb clinical trial is intended to support the design of our subsequent Phase III clinical trial for head applications, which we plan to call our REGION II clinical trial and which we plan to initiate in 2009, assuming a successful end-of-Phase II meeting with the FDA.

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We plan to conduct supportive safety and other studies in parallel with these clinical trials, and we expect to file a single NDA for applications on both head and non-head treatment locations with the FDA by mid 2010, assuming a successful end-of-Phase II meeting with the FDA and the successful completion of our Phase III clinical program.

### ***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 IIa, clinical trials in the BCC program with a total of 118 patients treated, and have a third Phase IIa trial of approximately 50 patients that is ongoing. We also plan to commence and complete a Phase IIb trial before we begin planning our Phase III 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 trials have focused on tumor-directed therapy for both facial and 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 local skin response 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 IIa, 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 local skin responses were mild to moderate. The most frequently reported local skin response was redness. Local skin responses typically resolved within four weeks and all local skin responses were resolved by the end of the trial. There were no drug-related serious adverse events reported.

The primary evaluation of efficacy was the 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 received treatment on days one and two, 71% of superficial BCCs out of 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.

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*PEP005-009 Clinical Trial.* Our PEP005-009 clinical trial is an ongoing Phase II dose escalation trial designed to determine the MTD of PEP005 Gel for BCC. A total of 33 patients are currently 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 II trials in superficial BCC patients to allow us to define an appropriate concentration and treatment regimen. We anticipate that the Phase III clinical program will likely include two identical vehicle-controlled pivotal trials. We plan to assess histologic clearance as well as clinical clearance. In addition, we expect to conduct an open-label, five-year, trial with active treatment only and without excision of the treatment sites. We expect to assess two-year recurrence rates at an interim point in this trial to form the basis for the NDA submission at that time. The remaining trial period (three years) is required to assess post-approval, long-term recurrence rates. Prior to initiation of the Phase III program, we will meet with the FDA to review preclinical, manufacturing and clinical data and to discuss the design of Phase III pivotal and other registration trials. We do not expect to commence the superficial BCC Phase III clinical program before 2010.

***Other Indications***

We believe that there are other potential uses for PEP005 in topical formulations for treatment of skin conditions, such as cutaneous warts and other non-melanoma skin cancers, such as SCC and nodular BCC. Of these potential indications, we have completed initial clinical trials for SCC in situ and nodular BCC. These initial clinical trials have demonstrated the potential of PEP005 to clear these skin cancers following two applications.

In addition, PEP005 has shown potential anti-cancer activity in preclinical tests against certain forms of leukemia and bladder cancers. We plan to pursue initial clinical trials of PEP005 as an intravenous therapy for certain forms of leukemia and as an intra-cavitary formulation for superficial forms of bladder cancer. We continue to support research in several of these areas with studies based on preclinical, clinical, regulatory and marketing criteria that we have established through our strategic planning processes. Once we demonstrate clinical proof of principle in one or more of these indications, we plan to collaborate on the further development and commercialization of these oncology products.

***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 design and administration services. Furthermore, in the future we may need to rely on other CROs to provide us with clinical trial design 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 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, 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.

**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

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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, 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; combination 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 of \$6.7 million was settled with 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 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. 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 do not expect to conduct further development of the Neosil intellectual property before calendar year 2009, if at all.

## **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 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 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.



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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 IIb and Phase III 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.

## **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. Initially, we anticipate that our sales representatives will target high prescribing dermatologists in the United States, and dermatologists and other clinicians who treat AK in Australia and New Zealand. We regard these markets as our target markets. We estimate that there are 10,000 board certified dermatologists in the United States and that high prescribers are well defined and can be targeted with a modest sales force. Accordingly, we believe a relatively modest sales organization can effectively penetrate this market. We intend to utilize various marketing strategies to enhance the market understanding and appreciation of the various attractive features of our products, including engendering and leveraging support of key opinion leaders in the field of dermatology, maintaining an active presence at scientific and industry conferences and developing a robust body of scientific data supporting the safety and efficacy of our products.

In addition, it is our intention to seek collaborative development and licensing arrangements with leading companies in geographic regions outside of our target markets in order to develop and commercialize products incorporating PEP005 in non-target markets. We believe this is the most effective way for us to leverage the maximum value for our product candidates consistent with the resources that we have available to us.

## **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), Efidex (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 actinic keratosis, 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



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

Once we obtain FDA clearance or approval for our products and begin to market them, we anticipate that Medicare will cover PEP005 Gel for AK under the Part D prescription drug benefit as a new class of patient self-administered therapy and will cover PEP005 Gel for BCC under the Medicare Part B program as it is an in-office, physician-applied treatment. 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. In addition, we cannot predict whether any of our drug candidates will be covered under Medicare Part B.

### **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 FDCA, 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.

*New Drug Application.* Approval of a New Drug Application, or 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;

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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 Good Manufacturing Practice, or 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, or GCP, regulations, including regulations for informed consent.

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

*Phase I:* 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 II:* 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 II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to run what is referred to as a Phase IIb evaluation, which is a second, confirmatory Phase II trial that could, if positive and accepted by the FDA, serve as a pivotal trial in the approval of a product candidate.

*Phase III:* These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III 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



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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 III 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 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 are utilizing the procedure called Special Protocol Assessment for PEP005 Gel for AK in connection with our Phase III 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 III 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 current Good Manufacturing Practice, or 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 FDCA, and failure to abide by these regulations can result in penalties, including the issuance

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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.

### *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 Therapeutics 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

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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.

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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.

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 I:* 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 II:* 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 II trials usually involve studies in a limited patient population.

*Phase III:* 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.

### **Facilities**

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. Our offices in Newstead consists of approximately 3,930 square feet, pursuant to leases that expire in June 2009 with one option to extend for an additional five-year term. 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 have also entered into a lease for approximately 4,240 square feet of additional office space in Newstead, Australia, expiring in September 2009. We believe that additional space will be available on commercially reasonable terms, as needed.

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**Employees**

As of September 30, 2008, we had 43 employees. We also retain numerous independent consultants and temporary employees to support our business needs.

**Legal Proceedings**

We believe that there are currently no claims that would have a material adverse impact on our financial position, operations or potential performance.



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The following table presents information about our executive officers and directors as of September 30, 2008.

**Executive Officers and Directors**

<b>Name</b>	<b>Age</b>	<b>Position</b>
Thomas G. Wiggans(1)	56	Chief Executive Officer, Chairman of the Board and Director
Eugene Bauer, M.D.	66	President and Chief Medical Officer and Director
David J.B. Smith	33	Company Secretary and Chief Financial Officer
Peter J. Welburn Ph.D.	56	Chief Scientific Officer, Vice President, Research & Development and General Manager, Australia
George W. Mahaffey	49	Chief Commercial Officer, Vice President, Sales & Marketing
Cheri A. Jones, M.S.	62	Vice President, Regulatory Affairs
Cherrell Hirst(1)(3)	63	Director
Joshua Funder	37	Director
Gary Pace, B.Sc. (Hons), Ph.D.(2)(3)	60	Director
James Scopa(2)(3)	49	Director
Michael Spooner(1)(2)(3)	51	Director

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

*Thomas G. Wiggans*, has served as our Chief Executive Officer since August 15, 2008 and as Chairman of our board of directors since October 2007. Previously, Mr. Wiggans served as Chief Executive Officer of Connetics Corporation, a biotechnology company, from 1994, and as Chairman of the board of directors of Connetics Corporation from January 2006, until December 2006 when Connetics Corporation was acquired by Stiefel Laboratories, Inc. From 1992 to 1994, Mr. Wiggans served as President and Chief Operating Officer of CytoTherapeutics, Inc., a biotechnology company. From 1980 to 1992, Mr. Wiggans served in various positions at Ares-Serono Group, a pharmaceutical company, including President of its U.S. pharmaceutical operations and Managing Director of its U.K. pharmaceutical operations. In addition, Mr. Wiggans is a member of the board of directors of Onyx Pharmaceuticals Inc., a publicly-held pharmaceutical company. Mr. Wiggans currently serves on the Board of Overseers of the Hoover Institution at Stanford University and the Board of Trustees of the University of Kansas Endowment Association. In addition, he is Chairman of the Biotechnology Institute, a non-profit educational organization. Mr. Wiggans received a B.S. in pharmacy from the University of Kansas and an M.B.A. from Southern Methodist University.

*Eugene Bauer, M.D.* has served as a member of our board of directors since June 2006 and as President and Chief Medical Officer since August 18, 2008. From November 2004 to June 2008, Dr. Bauer served as the Chief Executive Officer of Neosil, Inc., a dermatology company. Dr. Bauer is a Lucy Becker Professor, Emeritus, in the School of Medicine at Stanford University, a position he has held since 2002. He served as Vice President for Medical Affairs and Dean of the Stanford University School of Medicine from 1995 to 2001 and served as Chair of the Department of Dermatology at the Stanford University School of Medicine from 1988 to 1995. Dr. Bauer is also a co-founder and emeritus member of the board of directors of Connetics Corporation, a specialty pharmaceutical company acquired by Stiefel Laboratories in 2006. In addition, Dr. Bauer is a member of the board of directors of Protalex, Inc., a publicly-held biotechnology company, Echo Healthcare Acquisition Corp., a publicly-held acquisition vehicle of businesses in the healthcare industry, and Modigene, Inc., a publicly-held biopharmaceutical company. Dr. Bauer received a B.S.Med. and a M.D. from Northwestern University.

*David J.B. Smith* has served as our Chief Financial Officer since September 2, 2008 and our Company Secretary since April 2006. Previously Mr. Smith served as our Senior Director, Finance from April 2006 to September 2008 and as Financial Controller from July 2004 to March 2006. From April 2002 to June 2004, Mr. Smith held the position of Senior Analyst with Enertrade, a wholesale electricity trading corporation. From October 2000 to February 2002, Mr. Smith served as Group Corporate Accountant with Duke Energy International,

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an energy company, in London. Prior to that, from November 1999 to July 2000, Mr. Smith served as a financial accountant with Duke Energy International. Prior to November 1999, Mr. Smith held various positions with Ernst & Young. Mr. Smith is a chartered accountant and he received a Bachelor of Commerce from the University of Queensland, a Graduate Diploma in applied finance and investment from the Securities Institute of Australia and a Graduate Diploma in advanced accounting from the Queensland University of Technology.

*Peter J. Welburn, Ph.D.* has served as our Chief Scientific Officer and Vice President, Research & Development since April 2001 and as the General Manager, Australia of Peplin Limited since January 2007. Prior to joining Peplin Limited, from February 1991 to March 2001, Dr. Welburn was employed by SmithKline Beecham, a pharmaceutical and healthcare company, in its global strategic marketing group. Before moving to SmithKline Beecham in 1991, Dr. Welburn managed both Australian and international research and development programs for a number of compounds at Janssen Pharmaceuticals, a pharmaceutical company. Dr. Welburn received a Ph.D. from Cardiff University.

*George W. Mahaffey* has served as our Chief Commercial Officer and Vice President, Sales & Marketing since May 2007. Previously, from March 2004 to January 2007, Mr. Mahaffey was the Senior Vice President, Sales & Marketing at CoTherix, Inc., a biopharmaceutical company acquired by Actelion Ltd, a biopharmaceutical company, in 2006. From April 2000 to March 2004, Mr. Mahaffey served as Senior Director, Marketing & Business Development at Scios Inc., a biopharmaceutical company acquired by Johnson & Johnson in 2003. Prior to April 2000, Mr. Mahaffey held various sales, marketing and management positions at Neurex, Inc., a biotechnology company acquired by Elan in 1999, and DuPont, a chemicals and health care company. Mr. Mahaffey received a B.S. in chemical engineering at the University of Delaware and an M.B.A. from the University of South Florida.

*Cheri A. Jones, M.S.* has served as our Vice President, Regulatory Affairs since June 2006. Previously, from February 2003 to February 2006, Ms. Jones served as Vice President Regulatory Affairs at QLT U.S.A., Inc., a biopharmaceutical company. Prior to working at QLT U.S.A., Inc., Ms. Jones worked for Obagi Medical Products, Inc., a publicly-held pharmaceutical company, Valeant Pharmaceuticals International, a publicly-held pharmaceutical company, Alpharma Inc., a publicly-held pharmaceutical company, and Bristol-Myers Squibb Company, a publicly-held pharmaceutical company. Ms. Jones received a B.S. in health care administration and an M.S. in pharmaceutical marketing from St. John's College of Pharmacy. She is Regulatory Affairs Certified.

*Cherrell Hirst* has served as a member of our board of directors since August 2000. From August 2000 to October 2007, Dr. Hirst served as Chairman of our board of directors. Dr. Hirst is a medical doctor and until November 2001 was a practitioner in the area of breast cancer diagnosis. She serves as a director of Suncorp-Metway Ltd, a publicly-held banking, insurance, investment and superannuation company. Dr. Hirst was Chancellor of Queensland University of Technology from 1994 until September 2004. Dr. Hirst received a M.B.B.S. and a B.Ed.St. from the University of Queensland.

*Joshua Funder* has served as a member of our board of directors since October 2008. Dr. Funder is partner with GBS Venture Partners, a venture capital group, where he has been an investor since April 2004. Before joining GBS Venture Partners, Dr. Funder was Senior Manager, Corporate Strategy and Development at Infinity Pharmaceuticals, a drug discovery start-up in Boston, Massachusetts, starting in January 2003. From June to December 2004, Dr. Funder served as interim CEO of Proacta Inc. Dr. Funder also serves as a member of the board of directors of OPAL Inc. and Nuon Inc, Spinifex Pty Ltd, and Pathway Therapeutics Ltd. Dr. Funder received Bachelor of Science and Bachelor of Laws degrees from Melbourne University and a Master of Laws degree from the London School of Economics. He also holds a D.Phil in intellectual property for biotechnology from Oxford University.

*Gary W Pace, B.Sc. (Hons), Ph.D.* has served as a member of our board of directors since June 2004. Dr. Pace also serves as a member of the board of directors of QRxPharma Ltd., a clinical-stage specialty pharmaceutical company, which he founded in 2002. He is also a director of ResMed, Inc., a publicly-held medical device company, Transition Therapeutics Inc., a publicly-held biopharmaceutical company, and Celsion Corporation, a publicly-held biotechnology company. From 2000 to 2002, Dr. Pace was Chairman and Chief Executive Officer of Waratah Pharmaceuticals Inc., a biopharmaceutical company. From 1995 to 2001, Dr. Pace was President and Chief Executive Officer of RTP Pharma Inc., a pharmaceutical company. From 1993 to 1994, he was the founding President and Chief Executive Officer of Transcend Therapeutics Inc. (formerly Free Radical Sciences Inc.), a biopharmaceutical company. From 1989 to 1993, Dr. Pace was Senior Vice President of Clintec International, Inc., a manufacturer of clinical nutritional products. Dr. Pace received a B.Sc. with honors from the University of New South Wales and a Ph.D. from Massachusetts Institute of Technology.

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Dr. Pace was President and Chief Executive Officer of RTP Pharma Inc., a pharmaceutical company. From 1993 to 1994, he was the founding President and Chief Executive Officer of Transcend Therapeutics Inc. (formerly Free Radical Sciences Inc.), a biopharmaceutical company. From 1989 to 1993, Dr. Pace was Senior Vice President of Clintec International, Inc., a manufacturer of clinical nutritional products. Dr. Pace received a B.S. with honors from the University of New South Wales and a Ph.D. from Massachusetts Institute of Technology.

*James Scopa* has served as a member of our board of directors since June 2006. Mr. Scopa is a Managing Director of MPM Asset Management LLC, a Venture Capital Firm, a position he has held since May 2005. Previously, from June 2002 to May 2005, Mr. Scopa was a partner and co-Director of Healthcare Investment Banking at Thomas Weisel Partners. Mr. Scopa also served on the Investment Committee for Thomas Weisel Partners Health Care venture fund. Prior to joining Thomas Weisel Partners, he was a Managing Director and Global Co-Head of Healthcare Investment Banking at Deutsche Banc Alex. Brown from 1999 to 2002, having joined the former Alex. Brown & Sons in 1990. Mr. Scopa received an A.B. from Harvard College (Phi Beta Kappa), an M.B.A. from Harvard Business School and a J.D. from Harvard Law School.

*Michael Spooner* has served as a member of our board of directors since February 2004. Mr. Spooner is the Executive Chairman of Hunter Immunology Limited, a respiratory and immunology company. Mr. Spooner is also a non-Executive Director and Chairman of Mesoblast Limited, an adult stem cell company, a position he has held since December 2004. Previously, from November 2001 to November 2003, Mr. Spooner served as Managing Director and Chief Executive Officer of Ventracor Limited, an artificial heart company. He has been a partner and director of consulting services for Coopers & Lybrand (now PricewaterhouseCoopers) and PA Consulting Group, respectively. Mr. Spooner is a chartered accountant and received a Bachelor of Commerce from Queensland University of Technology.

There is no family relationship between any of our executive officers or directors.

*Recent Changes in Management*

*Michael D.A. Aldridge* served as our Managing Director, Chief Executive Officer and a Director from October 2003 through August 15, 2008, when he resigned from employment with us. Mr. Aldridge will continue to provide services to us as a consultant through May 15, 2009 (unless earlier terminated). Thomas G. Wiggans, our Chairman of the board, replaced Mr. Aldridge as Chief Executive Officer effective as of August 15, 2008.

*Philip K. Moody* served as our Chief Financial Officer, Vice President, Finance & Operations from October 2006 through September 2, 2008, when he resigned from employment with us. Mr. Moody will continue to provide services to us as a consultant through June 15, 2009 (unless earlier terminated). David J.B. Smith, our current Company Secretary and former Senior Director, Finance, replaced Mr. Moody as Chief Financial Officer effective as of September 2, 2008. We are in the process of finalizing compensation arrangements with Mr. Smith for this new role.

*Arthur P. Bertolino*, M.D., Ph.D., served as our Chief Medical Officer, Vice President, Medical Affairs, from April 2007 until June 30, 2008, when Dr. Bertolino resigned from his position with us. Gary Patou joined us in June 2008 as a consultant, acting as our Interim Chief Medical Officer in a non-executive role until August 18, 2008, when Eugene Bauer, one of our directors, assumed the roles of President and Chief Medical Officer. Dr. Patou will continue to provide services to us as a consultant through June 30, 2009.

**Composition of Board of Directors**

Our bylaws provide that our board of directors shall consist of between 5 and 12 members with the exact number of directors to be determined by resolution of the board of directors. Our board of directors has set the current authorized number at seven members. We currently have six board members and one vacancy. All of our current directors also serve as directors of Peplin Limited. Mr. Aldridge resigned as a member of our and Peplin Limited's board of directors in August 2008.

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Our board of directors is divided into three classes designated Class I, Class II and Class III, each with staggered three-year terms, as follows:

Class I consists of Dr. Pace and Mr. Scopa, whose term will expire at our annual meeting of stockholders to be held in 2011;

Class II consists of Dr. Hirst, Dr. Funder and Mr. Spooner, whose term will expire at our annual meeting of stockholders to be held in 2009; and

Class III consists of Dr. Bauer and Mr. Wiggins, whose term will expire at our annual meeting of stockholders to be held in 2010. At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Under Delaware law, our directors may be removed for cause by the affirmative vote of the holders of a majority of its voting stock.

Pursuant to a purchase agreement for shares and options entered into in May 2006, by and among Peplin Limited and MPM BioVentures IV-QP L.P., MPM BioVentures IV, L.P. and MPM Asset Management Investors BV4, or collectively, MPM, Peplin Limited undertook to procure that a resolution be put to stockholders to appoint Mr. Scopa, who is a general partner 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 our stockholders in June 2006 and Dr. Bauer, MPM's nominated person, was also elected by our stockholders in June 2006, and will each continue to serve as a director on the board of directors as indicated above and until their respective successors are duly elected by holders of our common stock.

Pursuant to a subscription agreement for shares and warrants entered into in August 2008, by and among us and the certain investors named therein, we agreed to use our best efforts to nominate and cause to be appointed as a Class II director on the our board of directors, Dr. Joshua Funder, as a designee of GBS Venture Partners Pty, an investor in the August 2008 financing. Dr. Funder joined our board following the closing of the August 2008 financing on October 23, 2008.

### **Committees of the Board of Directors**

We have established a standing audit committee, a compensation committee and a nominating and corporate governance committee. The audit committee consists of a majority of independent directors as further discussed under *Audit Committee* below, and we expect that it will consist solely of independent directors within the next year in accordance with SEC rules and regulations. Each of our compensation and nominating and corporate governance committees currently consists solely of independent directors as determined by our board of directors under applicable ASX standards. Our audit committee, compensation committee and nominating and corporate governance committee charters are available on our website, [www.peplin.com](http://www.peplin.com), under the Corporate Information section. The inclusion of our website address in this Information Statement does not include or incorporate by reference the information on our website into this Information Statement.

*Audit Committee.* Our audit committee currently consists of three directors, Dr. Hirst and Messrs. Spooner and Wiggins. Our board of directors has determined that Mr. Wiggins qualifies as an audit committee financial expert as defined under Item 407(d)(5) of Regulation S-K of the Securities Act of 1933. Mr. Wiggins assumed the role of Chief Executive Officer in August 2008 and, as a result, no longer qualifies as independent under applicable ASX guidelines. Our board of directors has determined to keep Mr. Wiggins on the audit committee for all or part of the next fiscal year until a replacement audit committee financial expert that is an independent director can be found. Mr. Spooner serves as the chair of the audit committee. Both our independent auditors and management periodically meet privately with our audit committee. We have adopted an audit committee charter intended to satisfy applicable SEC requirements.

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Our audit committee charter requires that the audit committee oversee our accounting and financial reporting processes. The primary duties of the audit committee consist of, among other things:

reviewing and pre-approving the engagement of our independent auditors to perform audit services and non-audit services;

evaluating the performance of our independent auditors and deciding whether to retain their services;

reviewing the independence of our independent auditors;

reviewing our annual and quarterly financial statements and reports and discussing the statements and reports with our independent auditors and management;

reviewing and approving all related-party transactions;

appointing an internal auditor and meeting with the internal auditor to discuss responsibilities, budget and staffing of our internal audit function;

reviewing with our independent auditors and management significant issues that may arise regarding accounting principles and financial statement presentation, including adequacy and effectiveness of our internal controls; and

establishing procedures for the receipt, retention and treatment of complaints received by us regarding, accounting, internal controls or auditing matters.

*Compensation Committee.* Our compensation committee currently consists of three directors, Dr. Pace and Messrs Scopa and Spooner. Mr. Scopa serves as the chair of the compensation committee. Each of these directors is independent under NASDAQ rules and qualifies as a non-employee director and an outside director for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 162(m) of the Internal Revenue Code, as amended, or the Code. We have adopted a compensation committee charter which outlines the compensation committee's primary duties to include, among other things:

determining the compensation and other terms of employment of our Chief Executive Officer and reviewing and approving corporate performance goals and objectives relevant to such compensation;

reviewing and approving the compensation and other terms of employment of our other executive officers;

reviewing and recommending compensation for non-management directors' service on our board of directors and any committees thereof;

reviewing and approving compensation for employees with a base salary greater than or equal to \$100,000;

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managing and reviewing our equity incentive plans, compensation plans and similar programs advisable for us, as well as modification or termination of existing plans and programs;

reviewing and approving appropriate insurance coverage for our officers and directors; and

managing and reviewing the terms of any employment agreements and severance arrangements for our executive officers.

*Nominating and Corporate Governance Committee.* Our nominating and corporate governance committee consists of four directors, Drs. Hirst and Pace and Messrs. Scopa and Spooner. Dr. Pace serves as the chair of the nominating and corporate governance committee. Each of these directors is independent under NASDAQ rules. We have adopted a nominating and corporate governance committee charter which outlines the nominating and corporate governance committee's primary duties to include, among other things:

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establishing standards for service on our board of directors and nominating guidelines and principles;

identifying individuals qualified to become members of our board of directors and recommending director candidates for election to our board of directors;

considering and making recommendations to our board of directors regarding its size and composition, committee composition and structure and procedures affecting directors;

establishing policies regarding the consideration of any director candidates recommended by our stockholders, and the procedures to be followed by stockholders in submitting such recommendations;

evaluating and reviewing the performance of existing directors; and

monitoring our corporate governance principles and practices and making recommendations to our board of directors regarding governance matters, including our certificate of incorporation, by-laws and charters of our committees.

### **Code of Business and Ethics**

Our board of directors has adopted a written Code of Business and Ethics for our directors, officers and employees. The code sets forth specific ethical policies and principles that apply to our directors, officers and employees designed to prevent wrongdoing and to promote:

honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

full, fair, accurate, timely and understandable disclosure in reports and documents that a registrant files with, or submits to, the Securities and Exchange Commission and in other public communications made by us;

compliance with applicable governmental laws, rules and regulations;

the prompt internal reporting of violations of the code to an appropriate person or persons identified in the code; and

accountability for adherence to the code.

A copy of our Code of Business and Ethics is posted on our website, [www.peplin.com](http://www.peplin.com), under the Corporate Information section. The inclusion of our website address in this Information Statement does not include or incorporate by reference the information on our website into this Information Statement. Any amendment or waiver of our Code of Business and Ethics relating to any of our executive officers or directors will be disclosed on our website, [www.peplin.com](http://www.peplin.com), under the Corporate Information section. In the case of a waiver, the nature of the waiver, the name of the person to whom the waiver was granted and the date of the waiver will also be disclosed.

*ASX Guidelines.* Corporate governance for companies whose securities are listed on the Australian Securities Exchange, or the ASX, like us, is governed by the ASX's Corporate Governance Council's Principles of Good Corporate Governance and Best Practice Recommendation, or ASX Guidelines. ASX Guidelines set out various corporate governance principles and best practice recommendations, and we are required under the listing rules of the ASX to provide a statement in our annual report or otherwise put out a release disclosing the extent to which we have followed the ASX Guidelines. On November 28, 2007, we issued a corporate governance statement that provided that our corporate governance

practices are largely consistent with ASX Guidelines and, to the extent applicable, Nasdaq guidelines.

**Director Compensation**

Our executive officers do not receive additional compensation for their service as directors. Mr. Wiggans and Dr. Bauer became executive officers following our fiscal year end of June 30, 2008. The table below summarizes the compensation received by our directors who were non-employees for the year ended June 30, 2008,



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which included Mr. Wiggans and Dr. Bauer. The following retainer fees are paid to our directors in Australian dollars, and the amounts shown below have been converted to U.S. dollars at an exchange rate of A\$1 for each U.S.\$0.9046, which was the average exchange rate published by the Reserve Bank of Australia for the period from July 1, 2007 through June 30, 2008.

Name	Fees Earned		Total (\$)
	Cash(1) (\$)	Option Awards(2) (\$)	
Thomas Wiggans, M.D.(3)(4)	54,568	50,871	105,439
Eugene Bauer, M.D.(3)(4)	45,230	0	45,230
Cherrell Hirst	55,784	0	55,784
Gary Pace, B.Sc. (Hons), Ph.D.(4)	45,230	0	45,230
James Scopa(4)	45,230	0	45,230
Michael Spooner(4)	45,230	0	45,230

- (1) Non-employee director retainer fees are determined by our board of directors within the aggregate limit for directors fees approved by the shareholders of Peplin Limited. Non-employee directors do not receive any retirement allowances or benefits, other than statutory superannuation entitlements, which are funded through a portion of the fees shown above. We pay no additional fees for attending meetings or for serving on committees.
- (2) The amounts shown are the amounts of compensation cost recognized by us in fiscal year 2008 related to the grants of stock options in fiscal year 2008 and prior fiscal years, as prescribed under the Statement of Financial Accounting Standards No. 123 (revised 2004), *Share Based Payment*, as amended, or SFAS No. 123R.

The grant date fair value of the options to purchase 25,000 shares of our common stock granted on January 16, 2008 to Mr. Wiggans was \$193,631, based on the Black-Scholes model of option valuation to determine grant date fair value as prescribed under SFAS No. 123R. The following assumptions were used in the Black-Scholes model: market price of stock: \$13.27; exercise price of option: \$13.27; expected stock volatility: 59%; risk-free interest rate: 3.74%; expected life: 6.25 years; dividend yield: 0%. The options were issued following approval of the grant by shareholders of Peplin, Inc. 25% of the options vest on the first anniversary of the grant date, with the remaining options vesting in 36 monthly installments beginning one month after the first anniversary of the grant date.

- (3) Mr. Wiggans replaced Mr. Aldridge as our Chief Executive Officer in August 2008 and as a result is no longer a non-employee director. Mr. Wiggans will remain as the Chairman of our board of directors and will continue to serve as a director. Dr. Bauer became our President and Chief Medical Officer in August 2008 and as a result is no longer a non-employee director. Dr. Bauer will remain on our board of directors as a director.
- (4) As of the end of our 2008 fiscal year, each of Drs. Bauer and Pace and Messrs. Scopa and Spooner each held options to acquire 5,000 shares of our common stock, and Mr. Wiggans held options to acquire 25,000 shares of our common stock. With the exception of Mr. Wiggans, who holds unvested options to acquire 25,000 shares of our common stock, none of our other non-employee directors held any unvested stock awards as of the end of our 2008 fiscal year.

In December 2007, the compensation committee engaged Setren, Smallberg & Associates, an independent consultant hired by us, to review director compensation, both the cash and equity components. The consultant used data from the Radford database for life sciences companies with less than 150 employees and a market cap of less than \$166 million (Radford), and the consultant's own internal data, which is based on a survey of biotechnology companies with less than 150 employees and an average market cap of less than \$200 million, in making its recommendations to the compensation committee. Based on this data and the consultant's recommendation, the compensation committee decided to set director compensation at the midpoint of the comparator group. The committee decided that the cash component of director compensation (other than the Chairman) was already generally at the midpoint of the comparator group and, as a result, no increase was made based on the review. The Chairman's compensation is higher than that at the midpoint of the comparator group, which the committee thought was justified as Mr. Wiggans possesses a unique background and experience of direct relevance to us, and spends more time on our business than board chairmen typically do.

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Based on the consultant's review and recommendation, in December 2007, the compensation committee determined that it should increase the amount of stock options awarded to our directors, as it provided considerably fewer options than the comparator groups. In order to be at or around the midpoint of the comparator groups, the compensation committee decided to set option grants at 25,000 upon appointment to the board of directors and up to an additional 15,000 options annually, and to provide the Chairman 50,000 additional options upon appointment and up to an additional 15,000 annually. In January 2008, we granted 25,000 options to Mr. Wiggans in connection with his appointment to the board of directors. In October 2008, following stockholder approval, we granted Mr. Wiggans 225,000 new option grants in connection with his employment as Chief Executive Officer.

For fiscal 2009, our non-employee directors will receive annual fees of approximately \$39,625 for their services on our board, except that our Chairman received annual retainer fees of approximately \$67,363. Our non-employee directors do not receive any additional fees for serving on our board or committees, or attending meetings and, as a result of Mr. Wiggans becoming our Chief Executive Officer in August 2008, he will no longer be paid annual retainer fees as our Chairman. In addition, Dr. Bauer will no longer receive annual retainer fees as a non-employee director, commencing in August 2008 when he became our President and Chief Medical Officer.

Newly appointed non-employee directors have historically been granted stock options in their first year of service on our board after approval of the stock option grants by the shareholders of Peplin Limited. Mr. Wiggans received options to acquire 25,000 shares of common stock on January 16, 2008 following his appointment to the board in October 2007.

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**COMPENSATION DISCUSSION AND ANALYSIS**

This Compensation Discussion and Analysis section discusses the compensation programs and policies for our executive officers and the compensation committee's role in the design and administration of these programs and policies and in making specific compensation decisions for our executive officers, including our named executive officers, which consisted of the following persons as of June 30, 2008: Michael D.A. Aldridge, our Chief Executive Officer, who resigned in August 2008; Philip K. Moody, our Chief Financial Officer and Vice President, Finance and Operations, who resigned in September 2008; Peter J. Welburn, our Chief Scientific Officer and Vice President, Research & Development; George Mahaffey, our Chief Commercial Officer, Vice President, Sales & Marketing; Cheri A. Jones, our Vice President, Regulatory Affairs; and Arthur P. Bertolino, our former Chief Medical Officer, Vice President, Medical Affairs, who resigned in June 2008.

On October 16, 2007, we were formed for the purpose of reorganizing our former parent company, Peplin Limited, into the United States. In connection with this reorganization, we acquired all the outstanding ordinary shares of Peplin Limited pursuant to a Scheme of Arrangement approved by the Federal Court of Australia and by Peplin Limited's shareholders in which we issued one share of our common stock for every 20 ordinary shares of Peplin Limited that were issued and outstanding. We also cancelled each of the outstanding options to acquire ordinary shares of Peplin Limited, including those that were listed on the Australian Securities Exchange, or ASX, and issued replacement options, appropriately adjusted to reflect the reorganization, representing the right to acquire shares of our common stock. We refer to these transactions as the Reorganization.

**Objectives and Elements of our Compensation Programs and Policies**

We believe that attracting and retaining highly skilled and motivated employees is critical to pursuing our mission and achieving our strategic goals for the benefit of our stockholders. We believe that our compensation policies are a key instrument in attracting, motivating and retaining these employees. The compensation committee's overall objective is to provide competitive compensation packages to our executives in order to attract and retain high-performing executive talent while promoting stockholder interests. To that end, the committee considers the company's performance over the past year in its determination of an executive's base salary and short-term incentive compensation (in the form of cash bonuses), as described more fully below.

The compensation of our executive officers is primarily comprised of base salaries, short-term incentives in the form of annual cash bonuses, long-term incentives in the form of both sign-on and annual grants of stock options, and certain severance benefits. Base salaries are based on the level of responsibilities and the experience of the individuals and form a stable part of each executive officer's compensation package. Annual cash bonuses provide incentives and rewards for our short-term performance. Stock options are based on a multiple of each executive's target annual cash bonus opportunity and provide incentives and rewards for long-term corporate performance through stock price appreciation. Severance benefits represent a relatively smaller portion of the overall package and promote job security.

Continuing from our 2007 fiscal year, during our 2008 fiscal year, the committee reviewed additional data regarding competitive or market comparable packages for our executives consistent with our international strategy focused on the North American continent and maintaining a pay level for Australian executives that resulted in relative equality among all of our executives. The committee determined that the executive officers' total compensation should be at least equal to the median compensation for the relevant comparables for their geographic area (the U.S. or Australia), with the possibility of an increase in short-term incentives (in the form of annual cash bonuses) in an amount that would place the executive's total cash compensation should be at the 75<sup>th</sup> percentile of such comparable if he or she is determined to have performed above the respective target goals in their action plan in any given year. Specifically, in fiscal 2008, the committee determined that total cash compensation (salary and target bonus) for U.S. executives should be at the median level of life science companies with less than 50 employees as set forth in the Radford database. For Australian-based employees, the committee determined to target the median compensation level of companies on the Mercer Australian Biotech Industry salaries and benefits survey results (which is published annually).

In fiscal 2008 and more recently, there have been a number of changes to our executive management team. Specifically, Michael D.A. Aldridge, who served as our Managing Director, Chief Executive Officer and a director from October 2003 through August 2008, resigned from employment with us. Mr. Aldridge will continue to provide services to us as a consultant through May 15, 2009 (unless earlier terminated). Thomas G. Wiggans, our Chairman of the board, replaced Mr. Aldridge as Chief Executive Officer in August 2008.

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Philip K. Moody served as our Chief Financial Officer, Vice President, Finance & Operations from October 2006 through September 2008, when he resigned from employment with us. Mr. Moody will continue to provide services to us as a consultant through June 15, 2009 (unless earlier terminated). Mr. Smith, our current Company Secretary and former Senior Director, Finance, has replaced Mr. Moody as Chief Financial Officer, although his compensation arrangements for this new role have not yet been finalized.

Arthur P. Bertolino, M.D., Ph.D., served as our Chief Medical Officer, Vice President, Medical Affairs, from April 2007 until June 2008, when Dr. Bertolino resigned from his position with us. Gary Patou joined us in June 2008 as a consultant, acting as our Interim Chief Medical Officer in a non-executive role until August 2008 when Eugene Bauer, one of our directors, assumed the roles of President and Chief Medical Officer. Dr. Patou will continue to serve as a consultant through June 2009.

We paid each of Mr. Aldridge and Mr. Moody severance payments and entered into new arrangements with each of Mr. Wiggans and Dr. Bauer, each as described below. We have not yet entered into any arrangements with Mr. Smith, as Chief Financial Officer. We did not make any additional payments to Dr. Bertolino in connection with his resignation, other than for accumulated leave pay and unpaid salary.

In addition, in connection with the Reorganization, the compensation committee undertook an internal review of options grants, with the goal of providing parity among the U.S. and Australian-based employees and executive officers. In connection with this internal review, the committee considered data included in the Radford database for life science companies with less than 50 employees. On August 7, 2007, our board of directors adopted the Peplin, Inc. 2007 Incentive Award Plan, which was subsequently approved by Peplin Limited's stockholders on October 1, 2007. Our employees, consultants and directors are eligible to receive awards under the 2007 Incentive Award Plan and, subsequent to the Reorganization, we began making our new-hire and annual employee equity grants under this plan.

Under the new plan, options granted in connection with commencement of employment vest on a monthly basis for three years commencing on the first anniversary of the date of grant, rather than on a yearly basis over a period of three years. On-going option grants vest on a monthly basis over a period of four years from the date of grant, rather than on a yearly basis over a period of three years. The option term was increased from five years to ten years. These changes were made to provide more flexibility in exercising options and obtaining value, and to align these option terms with options granted by companies in similar industries in the U.S.

### **Determination of Compensation**

The compensation committee is responsible for reviewing and approving the compensation arrangements for our executive officers, including the named executive officers. Our Chief Executive Officer attends meetings of the compensation committee when the committee is considering changes to compensation for the executive officers in order to present his analysis and recommendations as to performance awards with respect to the executive officers (other than himself). The committee takes his recommendation and analysis into account in making its determination. Our Chief Executive Officer leaves the meetings during any discussions or vote relating to his personal compensation.

While our fiscal year end is June 30, the compensation committee reviews the performance and compensation of the Chief Executive Officer and our other executive officers, including the named executive officers, on a calendar-year basis towards the end of each calendar year, usually in December. Our bonus determinations are based on performance of the executive officer and the company over the last calendar year. Any adjustment made to an executive officer's compensation, as a result of this annual review, typically takes effect on January 1 of the following calendar year.

### ***Annual Performance Reviews***

Annually, usually in December, or upon a new executive officer's commencement of employment, each executive officer agrees to an action plan which sets forth, among other things, specific company performance objectives for the area of responsibility of the executive and agreed to actions for the executive officer for the

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following calendar year. These action plans are formed as part of our annual business planning and budgeting activities and reflect the objectives of our corporate strategy. The results and actions to be achieved vary depending on the executive officer and from year to year and have historically included operational milestones, specific budget or plan parameters, target cost outcomes, personal accountabilities to be met or performance or safety outcomes targeted, although no single result or action has been considered material to compensation decisions. The action plan may also include the method or actions required to deliver the results specified. The action plan for our Chief Executive Officer is agreed to by our Chief Executive Officer and our full board of directors. The action plan for each of our other executive officers, including the other named executive officers, is agreed to by the executive officer and our Chief Executive Officer. The compensation committee generally does not review or comment on the actions plans of our named executive officers.

The action plans also incorporate a personal effectiveness review, which is completed by the Chairman of our board of directors in the case of the Chief Executive Officer, and by our Chief Executive Officer in the case of the other named executive officers, and reflects the level of achievement of the company performance objectives and agreed to actions for the completed calendar year, any particular achievements not previously planned or discussed, and opportunities for improvements against specific result areas or accountabilities. These personal effectiveness reviews are considered by the Chief Executive Officer in his recommendations to the compensation committee concerning the executive officers' cash bonuses and equity awards for the past calendar year and any salary increases for the upcoming calendar year, and as a result form a significant component of an executive officer's compensation arrangements. The compensation committee strongly considers the Chief Executive Officer's recommendations in making its recommendation to the full board of directors for approval.

***Competitive Market Data***

In addition to the annual performance reviews, in December 2007 the compensation committee began considering data from two sources in determining base salary increases and short and long-term incentive awards. The committee's objective was to review the continued validity of the compensation policies that were adopted in June 2006 based on an extensive review of executive compensation by a compensation consultant hired by us at that time, as further described below. In connection with the extensive review in June 2006, the committee determined that our executive officers' compensation should be at least equal to the median base salary and median incentive awards of the executives in the relevant markets.

In December 2007, for U.S.-based employees, the committee used data from the Radford database for life science companies with less than 50 employees, and determined that the threshold of total compensation for calendar year 2007 was generally not at the median level. Also in December 2007, for Australian-based employees, the committee used data from the Mercer Australian Biotech Industry salaries and benefits survey results (which is published annually), and determined that the threshold of total compensation for calendar year 2007 was generally not at the median level. We collectively refer to these sources as our Market Comparables. While the compensation committee uses the Market Comparables to set base salaries for executive, and generally tries to fall at or around the median level, in some instances based on experience of the individual, prior employment salaries or otherwise, the committee may determine that such person's salary should be above or below the median level, as applicable.

Based on a review of the Market Comparables in December 2007, the compensation committee determined that the compensation policies established by the committee in June 2006 in conjunction with reports prepared by Mercer Human Resource Consulting, an independent compensation consultant retained by us, were still valid. This compensation consultant review was undertaken by the compensation committee in June 2006 in connection with the relocation of our Chief Executive Officer from Australia to the United States and our executive officer hires in the U.S. market, including our Chief Financial Officer, our Vice President, Regulatory Affairs, our former Chief Medical Officer and our Interim Chief Medical Officer. The reports prepared by the compensation consultant in 2006 included Australian and U.S. market competitive compensation data for our Chief Executive Officer (Australian and U.S. data), Chief Financial Officer (Australian and U.S. data), Chief Medical Officer (U.S. data) and Vice President, Regulatory Affairs (U.S. data). For purposes of determining the compensation levels for our U.S.-based executives, including our Chief Executive Officer (who was then being relocated to the United States), the committee considered the U.S. market data. The U.S. market data was primarily gathered from the 2005 U.S. Top Five survey, which contains data from 395 U.S.-based publicly traded biopharmaceutical companies. The data for the surveys is submitted by the companies on an anonymous basis and is grouped in categories, such as location, stage of development and industry specialization. The data that the compensation committee reviewed was limited by the consultant to pharmaceutical and biotechnology companies with annual revenues of less than \$5.0 million, which essentially included companies at the same product development stage as us. We refer to these companies as our U.S. Top Five Survey Companies.

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Upon review of the compensation consultant's reports in June 2006, the committee found that U.S. executive pay levels were generally higher than Australian pay levels. Based on these reviews as well as the prior compensation of our U.S.-based executive officers, and following negotiations with these executive officers, the committee approved terms of employment agreements, which generally resulted in an increase in salaries for these executives, with our U.S.-based named executive officers as follows: Cheri Jones, M.S., our Vice President, Regulatory Affairs, in June 2006; Philip Moody, our Chief Financial Officer and Vice President, Finance and Operations, in September 2006; and Arthur Bertolino M.D., Ph.D., our former Chief Medical Officer and Vice President, Medical Affairs, in March 2007. In addition, based on the committee's review of the U.S. market data presented by the compensation consultant and in connection with his relocation to the United States, the committee also approved the terms of a new employment agreement with Michael Aldridge, our then Chief Executive Officer, in December 2006.

Mr. Moody's employment agreement with us was terminated in September 2008 when he resigned from his position with us. Mr. Aldridge's employment agreement with us was terminated in August 2008 when he resigned from his position with us. Dr. Bertolino's employment agreement with us was terminated in June 2008 when he resigned from his position with us.

### **Components of Compensation**

Executive compensation consists of the following components: base salaries, short-term incentives in the form of annual cash bonuses, long-term incentives in the form of both sign-on and annual stock option awards, and certain severance benefits, each as more fully described below.

#### ***Base Salary***

Base salaries are determined based on the executive officer's level of responsibilities and the experience of the individual. In order to attract and retain high-performing executive talent, the compensation committee believes it is important to provide base salaries that are at or about the median of the market in which we compete for the executive. Base salaries are reviewed annually (except in the case of new-hires or for promotions or other significant changes in responsibilities that happen during the fiscal year). In its annual review of base salaries, the committee assesses changes based on the scope and complexity of an executive officer's responsibilities. The committee considers the Chief Executive Officer's personal effectiveness reviews of the other named executive officers as well as the Chief Executive Officer's compensation recommendations for the other named executive officers in its determination. Previously, our Chairman provided the personal effectiveness review of the Chief Executive Officer, Mr. Aldridge, which the committee considered in determining the Chief Executive Officer's compensation. Going forward, the compensation committee will provide the personal effectiveness review of the Chief Executive Officer.

As described above under *Determination of Compensation*, base salaries for our U.S.-based named executive officers were initially set in connection with the employment agreements we entered into in 2006 and early 2007. These base salaries were determined in part based on the committee's review of the U.S. market data provided by the compensation consultant in June 2006, indicating that the base salary amounts for these executives fell between the 50<sup>th</sup> percentile and 75<sup>th</sup> percentile of the companies included in the U.S. Top Five Survey Companies. Also critical to determinations of base salary amounts for the U.S.-based executive officers were their compensation levels at their prior places of employment.

We have entered into employment agreements with all of our executive officers. These agreements establish an initial base salary, which is subject to adjustment at the discretion of our compensation committee, in some cases only upward adjustment, as more further described below.

We entered into an employment agreement with Mr. Aldridge, our former Chief Executive Officer, in December 2006, in connection with his relocation to the United States, which set a minimum base salary for our Chief Executive Officer at \$300,000. The compensation committee determined this amount in part based on its review of the compensation consultant's report on the U.S. market data, indicating that the \$300,000 base salary amount for the Chief Executive Officer fell between the 25<sup>th</sup> percentile and 50<sup>th</sup> percentile of the companies included in the U.S. Top Five Survey Companies. In December 2007, the compensation committee increased Mr. Aldridge's base salary to \$350,000 from \$300,000 (a 17% increase) based on his performance and the base salaries for his level.

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in the Radford database. Mr. Aldridge resigned from his position in August 2008, and his employment agreement with us was terminated. Mr. Aldridge will continue as a consultant through May 2009, during which time his outstanding but unvested options will continue to vest.

Mr. Wiggins replaced Mr. Aldridge as Chief Executive Officer in August 2008 pursuant to an employment agreement entered into between us and Mr. Wiggins which provides for a base salary of \$350,000, which is the same salary that Mr. Aldridge received prior to his resignation. The compensation committee determined this amount based on the fact that it was consistent with the pay determined by the committee as appropriate for the Chief Executive Officer.

For fiscal 2008, the compensation committee also reviewed data from the Market Comparables and decided not increase the base for Mr. Moody, our former Chief Financial Officer (\$280,000), Mr. Mahaffey, our Chief Commercial Officer, Vice President, Sales & Marketing (\$260,000), or Ms. Jones, our Vice President, Regulatory Affairs (\$245,000), as the committee felt that the base salaries set in the prior fiscal year for these executive officers were still competitive and that they were equal to or above the median base salaries set forth in the Radford database. The committee did increase the median base salary of Dr. Bertolino, our former Chief Medical Officer, from \$280,000 to \$300,000 in December 2007 in order to align it with the base salaries for his level as provided in the Radford database for Chief Medical Officers. Dr. Bertolino resigned in June 2008, and Dr. Bauer replaced Dr. Bertolino as Chief Medical Officer (and also took on the role of President) in August 2008 pursuant to an employment agreement between us and Dr. Bauer which provides for a base salary of \$290,000. The compensation committee determined this base salary based on Dr. Bertolino's previous salary and following negotiations with Dr. Bauer.

Mr. Moody resigned from his position as Chief Financial Officer in September 2008 and his employment agreement with us was terminated. Mr. Moody will continue as a consultant through June 15, 2009, during which time his outstanding but unvested options will continue to vest. Mr. Smith, our current Company Secretary and former Senior Director, Finance, replaced Mr. Moody as Chief Financial Officer in September 2008. We are in the process of finalizing full compensation arrangements with Mr. Smith, however, we have agreed to a base salary of \$180,843 for this new role.

During the compensation committee's December 2007 annual compensation review, the committee approved an increase in the base salary of Peter Welburn, Ph.D., our Chief Scientific Officer, Vice President, Research and Development, and General Manager, Australia, effective January 1, 2008, by 25%, to \$199,012 from \$158,500. This increase was recommended by the Chief Executive Officer and was based in large part on the additional role of General Manager, Australia, undertaken by Dr. Welburn, which he commenced in January 1, 2007 when our Chief Executive Officer relocated to the United States, and on the review of the Mercer Australian Biotech Industry survey results to align it to the median salaries for such position. As General Manager, in addition to his role as Chief Scientific Officer, Dr. Welburn is responsible for managing all Australian activities, including public relations, investor relations and commercial leadership.

***Short Term Incentives Annual Cash Bonuses***

Our annual cash bonuses reward our executive officers for our successful performance and each individual's contribution to that performance. Cash bonuses are generally determined and paid in December based on performance for that calendar year, rather than at the end of our fiscal year (which is June 30). Annual cash bonus amounts are determined at the subjective discretion of the committee at the end of the calendar year following the Chief Executive Officer's recommendation, which is based on our corporate results and the personal effectiveness reviews, as described more fully above under *Determination of Compensation*. The committee does not employ a formula in making its bonus determinations. Although the committee set total cash compensation (base salary and target cash bonus) in December 2007 to be at or around the median of Market Comparables, as applicable, the committee determined that our executive officers who out-perform in any given year should be eligible to receive annual cash bonuses in such amount as to place them at the 75<sup>th</sup> percentile for total cash compensation in the respective industry comparable. All of our named executive officers have total cash compensation that is at or around the median of compensation for their position in the Market Comparables.

The compensation committee set target annual bonuses for the 2007 and 2008 calendar years at 30% of base salary for each member of the executive management team other than Mr. Aldridge, whose target for 2008 was 40%. The committee increased Mr. Aldridge's target annual cash bonus opportunity to 40% of his base salary in December 2007 (an increase from 30% for the prior year) based on information provided to the compensation

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committee in a report from Setren, Smallberg & Associates, an independent consultant, in conjunction with a review of board of director compensation (which included Mr. Aldridge, our former Chief Executive Officer and a director) undertaken at the committee's request, and a review of the Radford database. The Setren report indicated that the bonus target practice for chief executive officers in the comparator group of firms reported a midpoint bonus target of 40%. As a result, compensation committee determined that it would be appropriate to increase Mr. Aldridge's bonus target to 40% to better align his total cash compensation with that of our competitors.

For the 2007 calendar year, Mr. Aldridge, Mr. Moody, Dr. Bertolino, Ms. Jones and Dr. Welburn received bonus awards of \$88,200, \$42,000, \$75,600, \$66,150 and \$52,500, respectively, representing approximately 29%, 15%, 27%, 27% and 30% of their respective base salaries. Mr. Mahaffey commenced his employment with us in May 2007 and received a bonus amount of \$49,920, representing 29% of his base salary, pro-rated to reflect his employment with us for only part of the calendar year. In making these bonus determinations, the committee noted successful achievement relating to:

completion of our PEP005-006 and PEP005-007 clinical trials for PEP005 (ingenol mebutate) Gel for AK;

exploring and understanding PEP005 (ingenol mebutate) Gel for AK in facial applications versus non-facial applications;

maintaining our current Good Manufacturing Practices, or cGMP, licensed manufacturing facility through 2007; and

completion of international capital raisings.

These factors were not pre-established performance targets tied to specific bonus payouts, but rather reflected our corporate results for the prior year, which the committee considered in making its bonus determinations. The committee also considered the Chief Executive Officer's recommendations which were based on his year-end personal effectiveness reviews of the executives' performance during the past year and, in the case of Mr. Moody, highlighted areas for improvement, which were reflected in his bonus determination of 15%, which was half of his target amount.

Subsequent to June 30, 2008, we entered into employment agreements with each of Mr. Wiggans and Dr. Bauer. Mr. Wiggans' agreement provides for a 2008 annual cash bonus of \$100,000, with a target range thereafter of \$125,000 to \$175,000 (which is effectively between 36% and 50% of his current base salary), to be determined by the compensation committee beginning in the 2009 calendar year and thereafter. Dr. Bauer's agreement provides a 2008 annual cash bonus of \$40,000, with a target award bonus amount of 30% of base salary thereafter, to be determined by the compensation committee. The compensation committee awarded each of Mr. Wiggans and Dr. Bauer a fixed bonus amount for 2008 in order to incentivize them to accept their positions, and due to the limited time remaining in the calendar to set meaningful performance targets and measure achievement against those targets.

Mr. Smith's short term incentive arrangement has not yet been finalized.

***Long-term Incentives - Stock Options***

Historically, we have only provided long-term incentives in the form of options to purchase shares of our common stock. These long-term incentives are designed to encourage retention of key employees and align the interest of our employees with the creation of stockholder value by creating long-term employee interest in our growth and stock price value.

Options are generally granted annually at the end of each calendar year, in connection with the executive officer's formal personal effectiveness review. The committee has sole discretion over the approval of options grants for our Chief Executive Officer. With respect to our other named executive officers, the committee recommends the amount of option grants to be made for the executive officers, and the grants are subsequently approved by the full board of directors. For the December 2007 grants to the U.S. named executive officers, the committee targeted the Black-Scholes value of annual stock options awards at two times the level of each executive officer's actual annual cash bonus for 2007, instead of two times the level of each executive officer's target cash bonus opportunity as in prior years to better align the option grants to an executive officer's performance. To create parity with the option





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grants to the U.S. executive officers, for the December 2007 grants to Mr. Welburn (who is not a resident in the U.S.), annual stock option awards are made as follows: one times the actual cash bonus paid in December 2007 to Mr. Welburn, plus one times the average of the target cash bonuses of the U.S. executive officers for 2007.

In addition, options are granted in connection with the commencement of employment. In fiscal 2008, the committee undertook a review of option grants, and determined that the authority to grant new-hire options should be delegated to the Chief Executive Officer.

In some cases, the compensation committee decides to award options to employees, including our executive officers, on a discretionary basis. In fiscal 2008, discretionary grants of 13,575, 30,000 and 20,000 were made to each of Messrs. Aldridge and Welburn and Ms. Jones to align their long-term compensation with that of their peer group within our company or as provided in the Market Comparables.

In addition, the employment agreements for each of Mr. Wiggans and Dr. Bauer, entered into in August 2008, provide for the grant of stock options of 225,000 and 100,000, respectively, each under our 2007 Incentive Award Plan. The employment agreement with Mr. Wiggans also provides for the grant of 225,000 shares of restricted stock, to be granted on or before October 30, 2008. These shares of restricted stock vest 25% on June 30, 2009, 25% on June 30, 2010, and 50% on June 30, 2011, if Mr. Wiggans continues to serve as the Chief Executive Officer through that date, or on the first day during Mr. Wiggans employment period (August 2008 – June 2010) following a period of 20 consecutive trading days during which the volume-weighted average price per share of our common stock for each day is equal to or greater than \$15.00 per share. These grants were approved by stockholders at the annual meeting held on October 6, 2008, and issued accordingly with an exercise price of \$6.24. It has also been agreed that Mr. Smith will receive sign on options of 50,000, also under our 2007 Incentive Award Plan.

Our policy is to set the exercise prices of our stock option grants equal to the market price on the date of grant. Prior to December 2006, market price was determined by calculating the volume weighted average closing share price of our stock on the ASX for the five trading days preceding the date of grant. In December 2006, we amended our policy so that market price on the date of grant is determined by calculating the volume weighted average closing share price of our stock on the ASX for the five trading days following the date of grant.

The following table sets forth the stock options granted to our named executive officers under the Peplin, Inc. 2007 Incentive Award Plan as it relates to their target annual cash bonus amounts, and any discretionary options that were granted to such executive officer in December 2007 in connection with the committee's annual review. The table also shows the amount of options the named executive officers would have received if we kept our prior formula of two times the target bonus amount.

<b>Name and Principal Position</b>	<b>2x Actual Cash Bonus(1)</b>	<b>Additional Discretionary Grant(2)</b>	<b>Total Actual Grant</b>	<b>2x Target Bonus(3)</b>
Michael D.A. Aldridge, Chief Executive Officer(4)	17,544	13,575	31,119	18,149
Philip K. Moody, Chief Financial Officer and Vice President, Finance and Operations(5)	8,469	0	8,469	16,939
George Mahaffey, Chief Commercial Officer, Vice President, Sales & Marketing(6)	10,067	0	10,067	10,415
Peter J. Welburn, Ph.D., Chief Scientific Officer and Vice President, Research & Development	13,317	30,000	43,317	13,317
Cheri A. Jones, M.S. Vice President, Regulatory Affairs	13,339	20,000	33,339	14,822
Arthur P. Bertolino, M.D., Ph.D., Former Chief Medical Officer(7)	15,245	0	15,245	16,939

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- (1) This amount reflects the number of options that each named executive officer, other than Mr. Welburn, would be entitled to receive based on two times the actual cash bonus paid in December 2007. For Mr. Welburn (who is not resident in the U.S.), this amount reflects one times the actual cash bonus paid in December 2007 plus one times the average of the target cash bonuses of the U.S. executive officers for 2007.
- (2) Discretionary grants were made to each of Messrs. Aldridge and Welburn and Ms. Jones to align their long-term compensation with that of their peer group within our company or as provided in the Market Comparables.
- (3) Target amounts represent two times the named executive officer's target bonus amount for 2007
- (4) Mr. Aldridge resigned from his position with us in August 2008. 33,334 of Mr. Aldridge's options issued were cancelled and 31,666 unvested options were forfeited. 39,725 of his options issued will continue to vest in accordance with the original option terms. All unvested options will be forfeited at the completion of the consultancy services
- (5) Mr. Moody resigned from his position with us in September 2008. 68,083 of his options will continue to vest while Mr. Moody is providing consulting services to us and 40,386 options that were not vested at the time of his resignation were forfeited.
- (6) Mr. Mahaffey commenced employment with us in May 2007. As a result, his target amounts are pro-rated to reflect the fact that he worked only part of the 2007 calendar year, from May 27, 2007 through December 31, 2007.
- (7) Dr. Bertolino commenced employment with us in March 2007 and was still employed in December 2007 when bonus and option decisions were made. Dr. Bertolino resigned from his position with us in June 2008, and all of his options lapsed.

The options outstanding as of the consummation of the Reorganization were options to purchase ordinary shares of Peplin Limited. Upon the completion of the Reorganization, in October 2007, these options were cancelled and replaced with new options to purchase shares of Peplin, Inc.'s common stock with substantially similar terms, but adjusted to give effect to the Reorganization, such that the number of shares underlying the options upon exercise were recalculated on a 1-for-20 basis, and a corresponding increase in the exercise price of each option was made by approximately a factor of 20. No other changes were made to the terms of the options, including the vesting schedule. These option grants were made under and governed by the terms of the 2007 Incentive Award Plan. We felt that, given the structure of company following the Reorganization, that it was most fair to our employees to adjust all outstanding options to reflect the Reorganization.

We evaluated the effect of the Reorganization on the fair value of existing options immediately before and after the Reorganization, and determined the effect was not material. In connection with the Reorganization, we were required for accounting purposes to revalue all options that had not vested prior to the Reorganization. As a result, we incurred an increase in stock compensation expense of approximately \$419,000, of which \$253,000 related to the named executive officers (other than Dr. Bertolino, who resigned in June 2008). This aggregate cost will be recognized by us over a period of approximately three years.

In connection with the Reorganization, the compensation committee undertook an internal review of options grants, with the goal of providing parity among the U.S. and Australian-based employees and executive officers. In connection with this internal review, the committee considered data included in the Radford database and on August 7, 2007, our board of directors adopted the Peplin, Inc. 2007 Incentive Award Plan. This plan was subsequently approved by Peplin Limited's stockholders on October 1, 2007. Our employees, consultants and directors are eligible to receive awards under the 2007 Incentive Award Plan and, subsequent to the Reorganization, we began making our new-hire and annual employee equity grants under this plan. Under this plan, options granted in connection with commencement of employment vest on a monthly basis for three years commencing on the first anniversary of the date of grant, rather than on a yearly basis over a period of three years. On-going option grants

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vest on a monthly basis over a period of four years from the date of grant, rather than on a yearly basis over a period of three years. The option term was increased from five years to ten years. These changes were made to provide more flexibility in exercising options and obtaining value, and to align these option terms with options granted by companies in similar industries in the U.S.

Prior to the adoption of the Peplin, Inc. 2007 Incentive Award Plan, grants of options of ordinary shares were made in accordance with the terms of our employee share option plan. Options granted under this plan generally had a five year term. Annual grants of options became exercisable with respect to one-third of the underlying shares on the grant date, or shortly thereafter, and one-third on each of the first and second anniversaries of the grant date, subject to the executive officer's continued employment. New-hire grants of options generally became exercisable with respect to one-third of the underlying ordinary shares on the anniversary of the employment commencement date, and one-third on each of the second and third anniversaries of the grant date, subject to the executive officer's continued employment. We are no longer making awards under this plan.

Our board of directors has adopted a policy that provides that in the event we undergo a change of control, unvested stock options held at the time of such change of control by our Chief Executive Officer and each officer who reports directly to the Chief Executive Officer, which includes all of the named executive officers, will become fully vested and exercisable. Our board has the right to amend or terminate this policy at any time. Change of control had not previously been defined for these purposes in the employment agreements of each of our named executive officers. However, for purposes of the employment agreements for each of Mr. Wiggins and Dr. Bauer, which we just entered into in August 2008, a change of control is generally defined as one of the following: (a) any person becomes the beneficial owner of our securities representing 50% or more of our combined voting power; (b) a change in the majority of the membership of our board occurs; (c) we are merged, consolidated or combined with another corporation or entity, there is a disposition, transfer, sale or exchange of all or substantially all of our assets, or we acquire the assets or stock of another entity and, in each case, and our stockholders prior to such transaction own less than 50% of the outstanding voting securities of the surviving entity, a majority of our directors were also directors of the successor entity and no one person or group owns 50% or more of the combined voting power of the successor entity; or (d) stockholder approval of a plan of our liquidation or dissolution.

***Perquisite and Other Benefits***

U.S. executives receive healthcare, medical and dental coverage, life insurance coverage and access to flexible spending accounts on the same basis as the benefits provided to all U.S. employees.

Our Australian executives receive no retirement allowances other than the statutory superannuation entitlements. As required by Australian law, we have contributed from all Australian employee's salary to defined contribution superannuation funds on behalf of all employees at an amount of 9% of the employee's salary. We permit employees to choose the superannuation fund into which the contributions are paid, provided the fund is appropriately registered. Australian employees also receive an additional superannuation contribution at 1% of base salary to be applied to life insurance. There are also limited salary packaging options for executives in the way they receive their base salary, these typically comprise vehicle leasing and superannuation.

We agreed to assist our Chief Executive Officer and U.S.-based named executive officers with reasonable relocation costs and expenses in connection with opening our principal place of business in Emeryville, California. We agreed to these costs in order to entice Mr. Aldridge to relocate from Australia to the United States and to entice the other U.S.-based named executive officers to join us and move from their homes in other states in the continental United States. Mr. Aldridge's employment agreement provided that we pay certain reasonable costs of relocation expenses, including one-way business class air travel from Brisbane to San Francisco, transportation and storage of furniture, a visa application and real estate agent services. In fiscal 2008, we paid an aggregate of \$968 for these services on behalf of Mr. Aldridge. In addition, we agreed to pay the costs, in an amount not to exceed \$25,000, of temporary accommodation in a furnished apartment for Mr. Aldridge. Mr. Aldridge resigned from his employment with us in August 2008.

Ms. Jones' employment agreement provides that we pay the reasonable cost of economy air travel from Colorado to San Francisco, transportation and storage of furniture and up to eight weeks temporary accommodations in a furnished apartment. Ms. Jones is also paid an amount each month, commencing on the date of her transfer to the San Francisco Bay area in June 2006 and continuing for a period of three years, to assist with her move to the San Francisco Bay area. Under this arrangement, we have agreed to pay her as follows: \$1,030 per month in the first

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year, \$515 per month in the second year and \$258 per month in the third year. Dr. Bertolino's employment agreement provided that we would pay for his relocation expenses from Michigan to the San Francisco Bay area, incurred in the first 24 months of his employment, upon presentation of a valid invoice or receipt of up to \$131,000 plus any resulting taxes. In fiscal 2008, we paid \$66,949 for these services on behalf of Dr. Bertolino (net of amounts he was required to reimburse for resigning within 18 months of commencing his employment). Dr. Bertolino resigned from his position with us in June 2008.

### ***Severance Benefits***

Each of our named executive officer's employment agreements provides for a severance payment if the executive officer is terminated by us without the prior notice of termination specified in the agreement. These severance payments range from one month's to six months' salary, based on position. The compensation committee determined that it was in our best interests to provide severance arrangements to our executive officers in order to keep their compensation arrangements competitive with those of other companies within our industry.

In August 2008, we entered into employment agreements with each of Mr. Wiggans, as Chief Executive Officer, and Dr. Bauer, as President and Chief Medical Officer. In addition to the severance payment for termination by us without prior notice, Mr. Wiggans' employment agreement provides for a change of control bonus of \$500,000. In addition, if Mr. Wiggans is terminated without cause on or after February 28, 2009 but prior to June 30, 2009, 112,500 of his stock options granted to him in August 2008 shall immediately vest. Furthermore, each of Mr. Wiggans and Dr. Bauer's employment agreements contain restrictive covenants. Mr. Wiggans and Dr. Bauer have each agreed to not solicit employees for a period of 18 months following termination of employment with us, and will at any time without our prior written approval use any information that constitutes a trade secret to solicit business away from our customers or vendors. Each has also agreed during their employment with us not to serve as an employee, consultant or director with any competitor of ours.

In addition to the foregoing, Mr. Aldridge's employment agreement, entered into in December 2006, provided him with a severance payment in the case of a change of control if he is not offered a continuing position of equivalent responsibility. This agreement was entered into in consideration of agreements generally with executives with Mr. Aldridge's level of responsibility in our industry. In August 2008, Mr. Aldridge resigned from his position with us. In connection with his resignation, we agreed to pay Mr. Aldridge a lump sum payment of \$175,000 (equal to six months base salary) and to pay COBRA premiums for Mr. Aldridge and his dependents for a period of six months following the date of termination. Mr. Aldridge agreed to remain as a consultant through May 2009, and his separation agreement with us provides that his outstanding options will continue to vest through such date. Mr. Aldridge will be paid a monthly fee of \$6,000 for up to 40 hours per month in consulting services, and an additional \$150 per hour for any additional hours worked during this period. In connection with his separation, we agreed to pay up to \$20,000 towards executive outplacement services and fees and expenses of counsel for Mr. Aldridge in connection with the negotiation of the separation agreement. Mr. Aldridge agreed to release us from all claims he may have under his employment agreement or otherwise.

Mr. Moody's employment agreement, effective as of October 2006, provided him with a severance payment in the case of a termination without cause. In September 2008, Mr. Moody resigned from his position with us. In connection with his resignation, we agreed to pay Mr. Moody a lump sum payment of \$140,000 (equal to six months base salary) and COBRA premiums for Mr. Moody and his dependents for a period of six months following the date of his termination. Mr. Moody agreed to remain as a consultant through June 15, 2009, and his separation agreement with us provides that his outstanding options will continue to vest through such date. Mr. Moody will be paid a monthly fee of \$1,333 for up to 20 hours per month in consulting services, and an additional \$66.67 per hour for any additional hours worked during this period. In connection with his separation, we agreed to pay up to \$7,500 towards executive outplacement services and fees and expenses of counsel for Mr. Moody in connection with the negotiation of the separation agreement. Mr. Moody agreed to release us from all claims he may have under his employment agreement or otherwise.

In connection with Dr. Bertolino's resignation in June 2008, we paid Dr. Bertolino accrued but unpaid salary and unused but accrued vacation time. Dr. Bertolino did not receive any severance payments, and all of his options lapsed on June 30, 2008, the last day of his employment. None of the exercise prices on his options were less than the outstanding market price at that time.

A description of the material terms of these agreements can be found under [Potential Payments Upon Termination or Change in Control](#).

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**Policy on Deductibility of Compensation**

The compensation committee annually reviews and considers the deductibility of executive compensation under Section 162(m) of the Code, which provides that we may not deduct certain compensation in excess of \$1,000,000 that is paid to certain individuals. We expect that compensation paid to our executive officers for fiscal year 2008 will qualify for deductibility because the compensation is below the threshold for non-deductibility provided in Section 162(m).

**Executive Compensation**

***Summary Compensation Table***

The following table provides information regarding the compensation awarded, paid to, or earned by each of our named executive officers for all services rendered to us for the fiscal years ended June 30, 2007 and June 30, 2008. The amounts included in the table are in U.S. dollars, and have been converted from Australian dollars at an exchange rate of A\$1 for each US\$0.9046, which was the average exchange rate published by the Reserve Bank of Australia for the period from July 1, 2007 through June 30, 2008.

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Name and Principal Position	Year	Salary(1) (\$)	Bonus(2) (\$)	Option Awards(3) (\$)	All Other Compensation(4) (\$)	Total (\$)
Michael D.A. Aldridge, Chief Executive Officer(5)	2008	323,958	88,200	279,900	0	692,058
	2007	251,171	87,175	352,267	52,752	743,365
Philip K. Moody, Chief Financial Officer and Vice President, Finance and Operations(6)	2008	280,000	42,000	283,855	0	605,855
	2007	210,000	0(7)	325,034	0	535,034
George Mahaffey, Chief Commercial Officer, Vice President, Sales & Marketing(8)	2008	222,103	49,920	416,822	0	688,845
	2007	23,833	0	17,045	0	40,878
Peter J. Welburn, Ph.D., Chief Scientific Officer and Vice President, Research & Development	2008	209,170	52,500	214,751	46,710	523,131
	2007	129,550	23,775	105,246	38,438	297,009
Cheri A. Jones, M.S. Vice President, Regulatory Affairs	2008	245,000	66,150	168,740	0	479,890
	2007	245,000	26,000	114,343	17,014	402,357
Arthur P. Bertolino, M.D., Ph.D. Former Chief Medical Officer(9)	2008	290,000	75,600	146,342	66,949	578,891
	2007	70,000	0(7)	98,064	11,640	179,704

- (1) The amounts shown include salary deferred under statutory superannuation entitlements for Australian employees, otherwise payable in cash during each of the two fiscal years.
- (2) While all other compensation listed in the table was earned for the fiscal years ended June 30, 2007 and June 30, 2008, cash bonuses are paid on a calendar year basis and not on the basis of the June 30 fiscal year. The amounts shown are the annual cash bonuses earned for the 2006 and 2007 calendar years and paid in December 2006 and December 2007, respectively.
- (3) The amounts shown are the amounts of compensation costs recognized by us in fiscal years 2007 and 2008 related to the grants of stock options in fiscal years 2007 and 2008 and prior fiscal years, as prescribed under SFAS No. 123R. For a discussion of valuation assumptions, see Note 11, Share Based Payments, of the Notes to our Consolidated Financial Statements. These amounts include additional compensation costs recognized by us in connection with the reissuance of stock options in connection with the Reorganization which occurred in fiscal 2008. For fiscal 2008, the total amount of the increase in compensation costs attributable to the named executive officers (to be incurred over the life of the options) was \$253,000. The following chart sets forth the additional compensation cost per person incurred in fiscal 2008 as a result of the Reorganization:

Name	Fiscal 2008 Compensation Cost Related to Reorganization(\$)
Michael D.A. Aldridge	(12,554)
Philip K. Moody	71,538
George Mahaffey	42,117

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Name	Fiscal 2008 Compensation Cost Related to Reorganization(\$)
Peter J. Welburn	13,919
Cheri A. Jones	4,329
Arthur P. Bertolino	49,231

(4) The amounts shown consist of our incremental cost for the provision to the named executive officers of certain specified prerequisites for fiscal 2008, as follows: \$66,949 in net relocation costs for Dr. Bertolino and \$46,710 in car allowance for Dr. Welburn. Relocation costs represent amounts that we agreed to pay in connection with each officer's relocation to the San Francisco Bay area pursuant to each officer's employment agreement. See Executive Compensation Employment Agreements for a description of the relocation costs we have agreed to pay. The car allowance paid to Dr. Welburn represents a benefit provided to Dr. Welburn in lieu of a portion of his base salary.

(5) Mr. Aldridge resigned from his position with us in August 2008. In connection with his resignation, we agreed to pay Mr. Aldridge a lump sum payment of \$175,000 (equal to six months base salary) and to pay COBRA premiums for Mr. Aldridge and his dependents for a period of six months following the date of termination. Mr. Aldridge agreed to remain as a consultant through May 2009, and his separation agreement with us provides that his outstanding options will continue to vest through such date. Mr. Wiggans, our Chairman of the Board, joined us as Chief Executive Officer in August 2008.

(6) Mr. Moody commenced employment with us in October 2006 and resigned in September 2008. In connection with his resignation, we agreed to pay Mr. Moody a lump sum payment of \$140,000 (equal to six months base salary) and pay COBRA premiums for Mr. Moody and his dependents for a period of six months following the date of termination. Mr. Moody agreed to remain as a consultant through June 15, 2009, and his separation agreement provides that his outstanding options will continue to vest through such date. Mr. Smith, our current company secretary and former Senior Director, Finance, joined us as Chief Financial Officer in September 2008.

(7) Mr. Moody and Dr. Bertolino did not earn a bonus for the 2006 calendar year because they were hired in October 2006 and March 2007, respectively.

(8) Mr. Mahaffey commenced employment with us in May 2007. Amounts shown for fiscal 2007 compensation are for the period from May 27, 2007 through June 30, 2007.

(9) Dr. Bertolino commenced employment with us in March 2007 and resigned from his position with us in June 2008. Gary Patou rejoined us in June 2008 as Interim Chief Medical Officer through August 2008, when Dr. Bauer, one of our directors, became our President and Chief Medical Officer.

**Grants of Plan-Based Awards**

The following table sets forth summary information regarding all grants of plan-based awards made to our named executive officers during the fiscal year ended June 30, 2008:

Name	Grant Date(1)	All Other Option Awards: Number of Securities Underlying Options(2)	Exercise or Base Price of Option Awards (\$/Sh)(3)(4)	Grant Date Closing Price of Option Awards (\$/Sh)(1)(3)(5)	Grant Date Fair Value of Stock and Option Awards(3)(6)
Michael D.A. Aldridge	01/16/2008	31,119	13.27	13.27	239,947
	10/31/2007	15,000	15.48	16.96	130,443
	10/31/2007	85,000	18.43	16.96	696,925
	10/31/2007	5,000	8.11	16.96	22,011
	10/31/2007	6,056	12.72	16.96	32,572
	10/31/2007	50,000	12.90	16.96	340,192
	10/31/2007	37,500	15.85	16.96	248,482



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Name	Grant Date(1)	All Other Option Awards: Number of Securities Underlying Options(2)	Exercise or Base Price of Option Awards (\$/Sh)(3)(4)	Grant Date Closing Price of Option Awards (\$/Sh)(1)(3)(5)	Grant Date Fair Value of Stock and Option Awards(3)(6)
Philip K. Moody	12/03/2007	8,469	13.81	13.81	67,578
	10/31/2007	90,000	12.90	16.96	645,374
	10/31/2007	10,000	15.85	16.96	66,261
George Mahaffey	12/03/2007	10,067	13.81	13.81	80,332
	10/31/2007	85,000	15.85	16.96	653,600
Peter J. Welburn, Ph.D.	12/03/2007	43,317	13.81	13.81	345,672
	10/31/2007	4,050	8.11	16.96	17,829
	10/31/2007	5,000	12.72	16.96	26,892
	10/31/2007	20,000	12.90	16.96	137,870
	10/31/2007	10,000	15.85	16.96	66,261
Cheri A. Jones, M.S.	12/03/2007	33,339	13.81	13.81	266,046
	10/31/2007	25,000	12.72	16.96	146,962
	10/31/2007	10,000	15.85	16.96	66,261
Arthur P. Bertolino, M.D., Ph.D.	12/03/2007	15,245	13.81	13.81	121,652
	10/31/2007	90,000	14.01	16.96	698,384

- (1) All options listed in the table as granted on October 31, 2007 relate to the issuance of options to purchase shares of common stock in exchange for already outstanding options to purchase common shares in connection with the Reorganization. The new options were issued on substantially similar terms (with no change in vesting or expiration, among other things) as the cancelled options, on a 1-for-20 basis, with a corresponding increase in the exercise price of each option by approximately a factor of 20. The effect of the Reorganization on the fair market value of these options was determined to not be material. However, for accounting purposes we did revalue all existing options that had not vested prior to the Reorganization. This resulted in an increase in stock compensation expense, as prescribed under SFAS 123R, of \$426,764, of which approximately \$169,554 related to options held by our named executive officers (other than Dr. Bertolino, whose options were cancelled on June 30, 2008 in connection with his resignation). All options issued in connection with the Reorganization in replacement of outstanding options were made under the 2007 Incentive Award Plan.
- (2) All options issued under the 2007 Incentive Award Plan, except for the options reissued in the Reorganization on October 31, 2007, vest monthly over four years following issuance, except for options granted upon commencement of employment, which vest 25% on the first anniversary of commencement of employment and monthly for three years thereafter, subject in each case to continued service with us.
- (3) All option grants under the 2007 Incentive Award Plan are made in U.S. dollars.
- (4) Our policy is to set the exercise prices of our stock option grants equal to the market price on the date of grant. Prior to December 2006, market price was determined by calculating the volume weighted average closing share price of our stock on the ASX for the five trading days preceding the date of grant. In December 2006, we amended our policy so that market price on the date of grant is determined by calculating the volume weighted average closing share price of our stock on the ASX for the five trading days following the date of grant.
- (5) Amounts shown are the closing prices of our stock on the ASX on the grant date.
- (6) The U.S. dollar value of the options shown represents the grant date fair value based on the Black-Scholes model of option valuation to determine grant date fair value, as prescribed under SFAS No. 123R. The actual value, if any, an executive may realize will depend on the excess of the stock price over the exercise price on the date the option is exercised. There is no assurance that the value realized by an executive will be at or near the value estimated by the Black-Scholes model. The following assumptions were used in the Black-Scholes model: market price of stock, \$6.94 to \$16.96; exercise price of option, \$7.37 to \$18.43; expected stock volatility, 53% to 62%; risk-free interest rate, 3.74% to 4.23% (based on the 10-year treasury bond rate); expected life, 1.23 to 6.02 years; dividend yield, 0%; expected forfeiture, 2.67%. These options vest and are generally exercisable in 48 monthly tranches beginning one month after the grant date.

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### **Employment and Consultancy Agreements**

*Employment Agreements.* All of our named executive officers are parties to employment agreements that establish an initial base salary, which is subject to adjustment (either up or down) at the discretion of our compensation committee, except that Mr. Aldridge's employment agreement provided for only upward discretion. In addition, the employment agreements we entered into in August 2008 with each of Mr. Wiggans and Dr. Bauer provide that the base salaries (\$350,000 for Mr. Wiggans and \$290,000 for Dr. Bauer) can only be increased unless any proposed decrease is in connection with a decrease of the base salaries of all of our executive officers, and then only by the percentage decrease of all such other executive officers.

Each named executive officer's employment agreement sets the executive's target annual cash bonus opportunity as a percentage of his or her calendar year base salary, subject to the discretion of the compensation committee. Actual annual cash bonus amounts have historically been determined at the subjective discretion of the committee at the end of each calendar year following consideration of the executives' personal effectiveness reviews. See Compensation Discussion and Analysis Components of Compensation Short Term Incentives Annual Cash Bonuses for a discussion of the named executive officers' bonuses.

The employment agreements for each of Mr. Aldridge, Dr. Bertolino and Ms. Jones provide for the payment of certain relocation costs associated with the executives' relocation to the San Francisco Bay area. See Compensation Discussion and Analysis Components of Compensation Perquisites and Other Benefits for a discussion of the relocation costs. Mr. Aldridge and Dr. Bertolino resigned from employment with us in August 2008 and June 2008, respectively.

The employment agreements also provide for certain severance payments and benefits. None of the employment agreements with our named executive officers have any specified terms and each of the named executive officers is an at-will employee, whose employment may be terminated by us at any time, for any reason or no reason, with or without cause, with written notice ranging from one to 12 months. See Potential Payments Upon Termination or Change in Control for a discussion of any payments or other benefits payable upon termination of the named executive officers' employment.

In addition, the employment agreements for each of Mr. Wiggans and Dr. Bauer provide for the grant of stock options of 225,000 and 100,000, respectively, each under our 2007 Incentive Award Plan.

For the grant to Mr. Wiggans, the options vest as follows:

50% on June 30, 2009, subject to continued employment (if Mr. Wiggans is terminated without cause on or after February 28, 2009 but prior to June 30, 2009, the first 50% of his options shall immediately vest);

and the remaining 50% in 12 monthly installments on the last day of each month from July 2009 through June 2010, subject to continued employment, provided that for the final nine monthly installments, Mr. Wiggans is only required to be serving as the Chief Executive Officer or the Chairman, but not both.

For the grant to Dr. Bauer, the options were treated as new hire options and vest 25% on the first anniversary of the grant date, with the remaining 75% vesting over 36 monthly installments through the fourth anniversary of the date of grant.

These options were approved by stockholders at the annual meeting on October 6, 2008 and granted that same day with an exercise price of \$6.24.

Mr. Wiggans will also receive 225,000 shares of restricted stock under his employment agreement which were granted on October 6, 2008 upon approval by stockholders at the annual meeting held on that date. These shares vest as follows:

50% shall vest in two equal installments on June 30, 2009, subject to continued employment, and June 30, 2010, subject to continued employment, provided that for the vesting of the second portion, Mr. Wiggans is only required to be serving as the Chief Executive Officer or the Chairman, but not both, from October 1, 2009 through the vesting date; and



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the remaining 50% shall vest on June 30, 2011, if Mr. Wiggans continues to serve as the Chief Executive Officer through that date, or on the first day during Mr. Wiggans employment period (August 2008 – June 2010) following a period of 20 consecutive trading days during which the volume-weighted average price per share of our common stock for each day is equal to or greater than \$15.00 per share.

**Outstanding Equity Awards at Fiscal Year End**

The following table sets forth summary information regarding the outstanding equity awards held by our named executive officers at June 30, 2008. Dr. Bertolino, one of our named executive officers, resigned from his position with us effective June 30, 2008. As a result, all of his outstanding options lapsed on June 30, 2008. Dr. Bertolino did not exercise any of his vested options prior to their lapse.

Name	Option Awards		Option Exercise Price per Share (\$)(1)	Option Expiration Date
	Number of Securities Underlying Unexercised Options Exercisable(1)(#)	Number of Securities Underlying Unexercised Options Unexercisable(1)(#)		
Michael D.A. Aldridge	3,245	27,874(2)	13.27	1/15/2018
	15,000	0	15.48	10/12/2010
	70,000	15,000(3)	18.43	10/12/2010
	5,000	0	8.11	12/31/2009
	6,056	0	12.72	12/31/2010
	33,334	16,666(4)	12.90	8/8/2011
	25,000	12,500(4)	15.85	12/31/2011
Philip K. Moody	1,062	7,407(5)	13.81	12/02/2017
	60,000	30,000(4)	12.90	12/31/2011
	6,667	3,333(4)	15.85	12/31/2011
George W. Mahaffey	1,260	8,807(5)	13.81	12/02/2017
	30,000	55,000(6)	15.85	6/11/2012
Peter J. Welburn, Ph.D.	5,418	37,899(5)	13.81	12/02/2017
	4,050	0	8.11	12/31/2009
	5,000	0	12.72	12/31/2010
	13,334	6,666(4)	12.90	8/8/2011
	6,667	3,333(4)	15.85	12/31/2011
	6,667	3,333(4)	15.85	12/31/2011
Cheri A. Jones, M.S.	4,170	29,169(5)	13.81	12/02/2017
	16,667	8,333(4)	12.72	12/31/2011
	6,667	3,333(4)	15.85	12/31/2011

(1) Amounts reflect the exchange of securities in the Reorganization on October 31, 2007.

(2) Remaining vest in 42 equal monthly installments to January 16, 2012.

(3) 100% of the remainder vest on October 13, 2008.

(4) 100% of the remainder vest on January 1, 2009.

(5) Remaining vest in 42 equal monthly installments to December 3, 2011.

(6) 30,000 vest May 25, 2009, and 25,000 vest May 29, 2010.

**Option Exercises and Stock Vested at Fiscal Year End**

None of our named executive officers exercised any stock options during the fiscal year ended June 30, 2008. We granted Mr. Wiggans 225,000 shares of restricted stock on October 6, 2008 in connection with his employment as Chief Executive Officer. We have never granted stock awards to our named executive officers.

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### **Potential Payments Upon Termination or Change-in-Control**

#### *Employment Agreements*

We have entered into employment agreements with each of our named executive officers which provide them with certain severance payments:

*Michael D.A. Aldridge.* Pursuant to the terms of Mr. Aldridge's employment agreement, we may terminate Mr. Aldridge's employment without cause after December 31, 2007, provided that we make a payment in lieu of the six-month notice period. If there is a change of control of Peplin Limited and its subsidiaries and Mr. Aldridge is not offered a continuing position of equivalent responsibility, we must pay Mr. Aldridge twelve months severance. We may terminate his employment immediately for cause without further compensation.

In August 2008, Mr. Aldridge resigned from his position with us. In connection with his resignation, we agreed to pay Mr. Aldridge a lump sum payment of \$175,000 (equal to six months base salary) and to pay COBRA premiums for Mr. Aldridge and his dependents for a period of six months following the date of termination. Mr. Aldridge agreed to remain as a consultant through May 2009, and his separation agreement with us provides that his outstanding options will continue to vest through such date. Mr. Aldridge will be paid a monthly fee of \$6,000 for up to 40 hours per month in consulting services, and an additional \$150 per hour for any additional hours worked during this period. In connection with his separation, we agreed to pay up to \$20,000 towards executive outplacement services and fees and expenses of counsel for Mr. Aldridge in connection with the negotiation of the separation agreement. Mr. Aldridge agreed to release us from all claims he may have under his employment agreement or otherwise.

*Philip K. Moody.* Pursuant to the terms of his employment agreement, we may terminate Mr. Moody's service without cause, provided that we make a payment in lieu of the six-month notice period specified in the agreement. We may terminate his employment immediately for cause without further compensation.

In September 2008, Mr. Moody resigned from his position with us. In connection with his resignation, we agreed to pay Mr. Moody a lump sum payment of \$140,000 (equal to six months base salary) and to pay COBRA premiums for Mr. Moody and his dependents for a period of six months following the date of termination. Mr. Moody agreed to remain as a consultant through June 15, 2009, and his separation agreement with us provides that his outstanding options will continue to vest through such date. Mr. Moody will be paid a monthly fee of \$1,333 for up to 20 hours per month in consulting services, and an additional \$66.67 per hour for any additional hours worked during this period. In connection with his separation, we agreed to pay up to \$7,500 towards executive outplacement services and fees and expenses of counsel for Mr. Moody in connection with the negotiation of the separation agreement. Mr. Moody agreed to release us from all claims he may have under his employment agreement or otherwise.

*Peter J. Welburn, Ph.D.* Pursuant to the terms of his employment agreement, we may terminate Dr. Welburn's service without cause, provided that we make a payment in lieu of the three-month notice period specified in the agreement, plus any accumulated leave. Upon termination for cause, Dr. Welburn may be entitled to accumulated leave payments, if any, and such termination shall be effective from the date of notice of termination submitted by us.

For purposes of Dr. Welburn's employment agreement, cause means if the executive:

is unable to perform his duties under the agreement for a continuous period of nine months in a 12-month period or is unable to perform his duties for separate periods in aggregate of 12 months in a 24-month period;

commits a willful breach or willfully neglects to perform his obligations under the employment agreement, company policy or company code of conduct;

commits any other act which would entitle us to dismiss him summarily; or

fails to observe or perform his duties under the employment agreement and fails to cure such failure within seven days of being instructed to do so in writing.



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*George W. Mahaffey and Cheri A. Jones, M.S.* Pursuant to the terms of their respective employment agreements, we may terminate Mr. Mahaffey's or Ms. Jones' service without cause, provided that we make a payment in lieu of the six-month or three-month notice period, respectively, specified in the respective agreement. We may terminate the executive's employment immediately for cause without further compensation.

For purposes of the employment agreements discussed above, "cause" means if the executive:

engages in misconduct;

commits a willful breach or willfully neglects to perform his obligations under the employment agreement;

fails to observe or perform his duties under the employment agreement and fails to cure such failure within seven days of being instructed to do so in writing;

is convicted of or pleads *nolo contendere* to any felony or crime of moral turpitude; or

refuses to carry out the lawful directions of the board of directors of the employing entity or a supervisor, as specified in the employment agreements.

*Arthur P. Bertolino, M.D., Ph.D.* Pursuant to the terms of Dr. Bertolino's employment agreement, if we terminate Dr. Bertolino's employment without cause, or Dr. Bertolino terminates his employment because there is a change of control of Peplin Operations USA, Inc. or the principal site for his duties are relocated to outside of the United States, we must pay Dr. Bertolino a lump sum cash payment equal to twelve months base salary. We may terminate his employment immediately for cause without further compensation. In addition, in accordance with the terms and conditions of Dr. Bertolino's sign-on option grant, the shares underlying the grant fully accelerate in the case of a change of control. Dr. Bertolino resigned from his position with us effective June 30, 2008. Pursuant to the terms of his employment agreement with us, we were not required to make any payments to Dr. Bertolino resulting from his termination of employment, and no payments were made in connection with his resignation.

Pursuant to Mr. Aldridge's and Dr. Bertolino's resignations, we entered into employment agreements with Mr. Wiggans, as our Chief Executive Officer and Chairman of the Board, and Dr. Bauer, as President and Chief Medical Officer as described below. We have not yet finalized arrangements with Mr. Smith, our new Chief Financial Officer.

*Thomas G. Wiggans and Eugene Bauer, M.D.* Pursuant to the terms of their respective employment agreements, we may terminate Mr. Wiggans or Dr. Bauer's service with or without cause upon giving written notice to the executive specifying the effective date of the termination which cannot be not less than thirty days or more than forty days following the date notice is given. The executive can also terminate his employment with us for good reason or without good reason at any time upon giving written notice to us specifying the effective date of the termination which cannot be not less than thirty days or more than forty days following the date notice is given. In the event that we terminate the executives' employment without cause after February 28, 2009, or the executive terminates his employment for good reason, we will be required to make a severance payment equal to his base salary in effect immediately preceding the termination date for a period of six months following termination, and pay for continuation of COBRA premiums for a period of six months following termination.

For purposes of the employment agreements discussed above, "cause" means the board of directors' reasonable determination that the executive has:

been convicted of or pled guilty or not contest to any felony;

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committed one or more acts of theft, embezzlement or misappropriation against us; or

materially breached his obligations under his respective employment agreement and the breach has not been remedied within 30 days of delivery to executive by us of a written notice specifically identifying the breach.

In addition, if Mr. Wiggins is terminated without cause on or after February 28, 2009 but prior to June 30, 2009, 112,500 of his stock options granted to him in October 2008 shall immediately vest. Mr. Wiggins



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employment agreement also provides for a change of control bonus of \$500,000, payable upon the occurrence of a change of control, and the employment agreements for each of Mr. Wiggins and Dr. Bauer provide for acceleration of all outstanding stock options or restricted stock upon the occurrence of a change of control. For purposes of these employment agreements, a change of control is generally defined as one of the following: (a) any person becomes the beneficial owner of our securities representing 50% or more of our combined voting power; (b) a change in the majority of the membership of our board occurs; (c) we are merged, consolidated or combined with another corporation or entity, there is a disposition, transfer, sale or exchange of all or substantially all of our assets, or we acquire the assets or stock of another entity and, in each case, and our stockholders prior to such transaction own less than 50% of the outstanding voting securities of the surviving entity, a majority of our directors were also directors of the successor entity and no one person or group owns 50% or more of the combined voting power of the successor entity; or (d) stockholder approval of a plan of our liquidation or dissolution.

In addition, each of Mr. Wiggins and Dr. Bauer's employment agreements contain restrictive covenants. Mr. Wiggins and Dr. Bauer have each agreed to not solicit employees for a period of 18 months following termination of employment with us, and will at any time without our prior written approval use any information that constitutes a trade secret to solicit business away from our customers or vendors. Furthermore, each has agreed during their employment with us not to serve as an employee, consultant or director with any competitor of ours.

In accordance with the requirements of the rules of the Securities and Exchange Commission, the following table presents our reasonable estimate of the benefits payable to the named executive officers (other than Dr. Bertolino who resigned from his position with us in June 2008; no payments were made to Dr. Bertolino in connection with the termination of his employment) under our agreements assuming that:

a change of control occurred on June 30, 2008, the last business day of fiscal year 2008;

for Mr. Aldridge, a change of control and termination of employment occurred on June 30, 2008, the last business day of fiscal year 2008; and

a termination without the required notice occurred on June 30, 2008, the last business day of fiscal year 2008.

Excluded are benefits provided to all employees, such as accrued vacation, and benefits provided by third-parties under our life and other insurance policies. While we have made reasonable assumptions regarding the amounts payable, there can be no assurance that in the event of a qualifying termination in connection with a change of control, the named executive officers will receive the amounts reflected below.

Name	Trigger	Cash	Value of Potential	Total
		Severance(1)(2) (\$)	Acceleration(2)(3) (\$)	Value(2)(4) (\$)
Michael D.A. Aldridge	Change of Control	0	0	0
	Change of Control and Qualifying Termination	350,000	0	350,000
	Termination Without Required Notice Period	175,000	0	175,000
Philip K. Moody	Change of Control	0	0	0
	Termination Without Required Notice Period	140,000	0	140,000
George Mahaffey	Change of Control	0	0	0
	Termination Without Required Notice Period	130,000	0	130,000
Peter J. Welburn, Ph.D.	Change of Control	0	0	0
	Termination Without Required Notice Period	58,237(2)	0	58,237
Cheri A. Jones, M.S.	Change of Control	0	0	0
	Termination Without Required Notice Period	61,250	0	61,250



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- (1) Represents the dollar value of cash severance based upon the monthly salary for the executive officer, multiplied by the number of months required by the notice period specified in the agreement.
- (2) Amounts have been converted from Australian dollars using the foreign currency exchange rate as of June 30, 2008.
- (3) Amounts shown represent the aggregate value of the acceleration of vesting of the executive officer's unvested options, based on the spread between the closing price of our common stock of \$7.51 on June 30, 2008 and the options' exercise prices. All values are listed as zero, as none of the option exercise prices were below the market price of our common stock on June 30, 2008.
- (4) Excludes the value to the executive of the continued right to indemnification by us. Executive officers will be indemnified by us and will receive continued coverage under our directors' and officers' liability insurance (if applicable).

***Option Acceleration Policy***

Our board of directors has adopted a policy that provides that in the event of a change of control, with respect to our Chief Executive Officer and those officers who report directly to our Chief Executive Officer, which includes each of our named executive officers, each officer's unvested options held at the time of such change of control will become fully vested and exercisable. Our board of directors has the right to amend or terminate this policy at any time. The term change of control has not been defined for these purposes. Our board of directors in its discretion determines whether a change of control has occurred under this policy, except that the employment agreements of Mr. Wiggans and Dr. Bauer, which we entered into in August 2008, define change of control for these purposes.

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The following table sets forth certain information with respect to the beneficial ownership of our common stock as of November 10, 2008 with respect to:

each person, or group of affiliated persons, who is known by us to own beneficially more than 5% of our common stock;

each of our named executive officers;

each of our directors;

all of our executive officers and directors as a group; and

each selling stockholder.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. Except as indicated in the footnotes to this table and pursuant to state community property laws, each stockholder named in the table has sole voting and investment power for the shares shown as beneficially owned by such stockholder. Percentage of ownership is based on 15,141,129 shares of common stock outstanding on November 10, 2008 including the number of shares offered hereby. The number of shares of common stock outstanding used in calculating the percentage for each listed person and entity (and for all executive officers and directors as a group) includes common stock underlying options held by that person or entity (or by all executive officers and directors as a group, as the case may be) that are exercisable within 60 days of November 10, 2008, but excludes common stock underlying options held by any other person or entity.

The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale or other disposition of any of the shares. The securities covered hereby may be offered from time to time by the selling stockholders.

Unless otherwise indicated in the footnotes, the address of each of the individuals named below is: c/o Peplin, Inc., 6475 Christie Avenue, Emeryville, California 94608.

Beneficial Owner	Shares Beneficially Owned		Shares of Common Stock Being Offered(1)	Shares Beneficially Owned After the Offering	
	Number	Percent		Number	Percent
<b>Directors and Officers</b>					
Thomas G. Wiggans	261,388(2)	1.7%		261,388	1.7%
Eugene Bauer, M.D.	15,000(3)	*		15,000	*
Philip K. Moody	68,083(4)	*		68,083	*
George W. Mahaffey	32,730(5)	*		32,730	*
Cheri A. Jones, M.S.	44,035(6)	*		44,035	*
David J.B. Smith	19,678(7)	*		19,678	*
Peter J. Welburn, Ph.D.	50,789(8)	*		50,789	*
Cherrell Hirst	38,566(9)	*		38,566	*
Gary Pace, B.Sc.(Hons), Ph.D.	32,025(10)	*		32,025	*
Joshua Funder		*			*

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Beneficial Owner	Shares Beneficially Owned		Shares of Common Stock Being Offered(1)	Shares Beneficially Owned After the Offering	
	Number	Percent		Number	Percent
James Scopa	3,679,021(11)	23.1%	1,543,540	2,135,481	13.7%
Michael Spooner	24,001(12)	*		24,001	*
Michael D.A. Aldridge	145,486(13)	1.0%		145,486	1.0%
All executive officers and directors as a group (13 persons)	4,410,802(14)	27.6%	1,543,540	2,867,262	18.4%
<b>5% or Greater Stockholders</b>					
Entities affiliated with MPM BioVentures IV LLC c/o MPM Bioventures IV LLC 200 Clarendon Street Boston, MA 02116	3,659,021(15)	23.0%	1,543,540(16)	2,115,481	13.6%
Entities affiliated with Acorn Capital Limited c/o Acorn Capital Limited Level 12, 90 Collins Street Melbourne Victoria 3000, Australia	1,129,906(17)	7.4%		1,129,906	7.4%
Entities affiliated with Orbis Global Equity Fund Limited LPG Building, 34 Bermudiana Road Hamilton HM 11, Bermuda	1,490,561(18)	9.8%	110,252(19)	1,380,309	9.1%
Asia Union Investments Pty Limited	1,426,356(20)	9.4%	228,592	1,197,764	7.9%
New Enterprise Associates 12, Limited Partnership	1,058,432(21)	6.9%	1,058,432	0	*
GBS Venture Partners PTY Ltd as Trustee for GBS BioVentures IV	1,904,960	12.2%	1,904,960	0	*
<b>Other Selling Stockholders</b>					
Warakirri Endeavor Fund	44,100	*	44,100	0	*
Construction and Building Union Superannuation Fund	373,036	2.4%	373,036	0	*
Intech Australia Shares High Alpha Trust	44,100	*	44,100	0	*
GE Capital Equity Investments, Inc.	39,325	*	39,325	0	*
Oxford Finance Corporation	16,662	*	16,662	0	*

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- \* Less than 1% of the outstanding shares of common stock.
- (1) Includes shares of our common stock underlying the exercise of warrants issued in the August 2008 Financing Transaction.
  - (2) Includes 225,000 shares of restricted stock issued on November 6, 2008.
  - (3) Dr. Bauer has the right to acquire these shares of common stock pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (4) Mr. Moody has the right to acquire these shares of common stock pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (5) Mr. Mahaffey has the right to acquire these shares of common stock pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (6) Ms. Jones has the right to acquire these shares of common stock pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (7) Mr. Smith has the right to acquire these shares of common stock pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (8) Dr. Welburn has the right to acquire these shares of common stock pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (9) Includes 15,933 shares of common stock Ms. Hirst has the right to acquire pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (10) Includes 22,775 shares of common stock Dr. Pace has the right to acquire pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (11) Includes: 20,000 shares of common stock Mr. Scopa has the right to acquire pursuant to outstanding options exercisable within 60 days of November 10, 2008 and (a) 2,865,346 shares of common stock, (b) 385,885 shares of common stock subject to outstanding warrants that are fully exercisable, and (c) 407,790 shares of common stock subject to outstanding replacement options exercisable within 60 days of November 10, 2008, held, in the case of each of the securities described in clauses (a), (b), and (c) of this paragraph, by entities affiliated with MPM BioVentures IV LLC. Mr. Scopa is a managing director of MPM BioVentures IV LLC. Mr. Scopa disclaims beneficial ownership of the securities held by MPM BioVentures IV LLC or its affiliates, except to the extent of his pecuniary interest therein. See footnote 15 below for additional information regarding the holdings of entities affiliated with MPM BioVentures IV LLC.
  - (12) Includes 20,154 shares of common stock Mr. Spooner has the right to acquire pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (13) Includes 140,886 shares of common stock Mr. Aldridge has the right to acquire pursuant to outstanding options exercisable within 60 days of November 10, 2008.
  - (14) Includes 847,852 shares of common stock subject to outstanding options exercisable within 60 days of November 10, 2008.
  - (15) Includes: (a) 2,865,346 shares of common stock, (b) 385,885 shares of common stock subject to outstanding warrants that are fully exercisable, and (c) 407,790 shares of common stock subject to outstanding replacement options exercisable within 60 days of November 10, 2008, held in each case by entities affiliated with MPM BioVentures IV LLC. The entities affiliated with MPM BioVentures IV LLC are MPM BioVentures IV-QP, L.P., MPM BioVentures IV GmbH & Co. Beteiligungs, KG and MPM Asset Management Investors BV4 LLC, each of which holds 2,685,521, 103,461 and 76,364 shares of common stock, warrants to purchase 361,668, 13,933 and 10,284 shares of common stock and replacement options to purchase 382,198, 14,724

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- and 10,868 shares of common stock, respectively. The voting and disposition of the shares of common stock and options held by these entities is determined by the managing directors of MPM BioVentures IV LLC, which is a direct or indirect general partner or managing limited partner, as applicable, of these entities. According to information provided by the shareholder, Ashley Dombkowski, Luke Evnin, Ansbert Gadicke, William Greene, Vaughn M. Kailian, Steven St. Peter, Jim Scopa, who is a member of our board of directors, and John Vander Vort are managing directors of MPM BioVentures IV LLC and share voting and investment power with respect to these shares, each of whom disclaims beneficial ownership of these shares, except to the extent of any pecuniary interest therein. In addition, Dr. Patou, one of our consultants, is a managing director of MPM Asset Management LLC. As an executive partner, 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.
- (16) Includes 1,446,672 shares offered by MPM Bioventures IV-QP L.P., 55,732 shares offered by MPM Bioventures IV GMB & Co. Beteiligungs KG, and 41,136 shares offered by MPM Asset Management Investors BV4LLC.
- (17) Includes: (a) 1,086,124 shares of common stock and (b) 43,782 shares of common stock subject to outstanding replacement options exercisable within 60 days of November 10, 2008, held of record by nominee and trustee companies on behalf of Acorn Capital Limited, in its capacity as a discretionary investment manager to certain superannuation funds, pooled superannuation trusts, managed investment schemes and investment management agreements. Acorn Capital Limited has sole voting and dispositive power over these shares. According to information provided by the shareholder, Robert Brown, David Bryant, Barry Fairley, Ian Ferres, Barrie Laws and Robert Officer, the directors of Acorn Capital Limited, and Peter Russell, the Senior Industrial Analyst of Acorn Capital Limited, share voting and investment power with respect to these shares, each of whom disclaims beneficial ownership of these shares, except to the extent of any pecuniary interest therein.
- (18) Includes: (a) 1,371,806 shares of common stock, (b) 27,563 shares of common stock subject to outstanding warrants that are fully exercisable and (c) 91,192 shares of common stock subject to outstanding replacement options that are fully exercisable held by entities affiliated with Orbis Global Equity Fund Limited. The entities affiliated with Orbis Global Equity Fund Limited are Orbis Optimal SA Fund Limited, Orbis SICAV-Global Equity Fund, Orbis Optimal Global Fund, L.P., Orbis MIS Orbis Global Equity Fund, Orbis SICAV Asia ex Japan Equity Fund, Orbis MIS Orbis/SM Australia Equity Fund and G.A. Fund L Equity Deep Value World TP, each of which holds 25,250, 79,374, 7,700, 61,273, 205,619, 233,222 and 12,850 shares of common stock, respectively. According to information provided by the shareholder, Simon Marais, Chief Executive Officer and director of Orbis Investment Management (Australia) Pty has voting and investment power with respect to the shares held by Orbis MIS Orbis/SM Australia Equity Fund and William Gray, President and director of Orbis Investment Management Limited, has voting and investment power with respect to the shares held by Orbis Global Equity Fund Limited and the other entities affiliated with Orbis Global Equity Fund Limited, each of whom disclaims beneficial ownership of these shares, except to the extent of any pecuniary interest therein.
- (19) All 110,252 shares of Common Stock are being offered by Orbis MIS-Orbis/SM Australia Equity.
- (20) Includes 39,185 shares of common stock subject to outstanding options exercisable within 60 days of November 10, 2008. According to information provided by the shareholder, Barbara Ann Abbott, Christopher Abbott and Rosalind Phyllida Abbott, are directors of Asia Union Investments Pty Limited, and share voting and investment power with respect to these shares, each of whom disclaims beneficial ownership of these shares, except to the extent of any pecuniary interest therein.
- (21) NEA 12 GP, LLC is the sole general partner of NEA Partners 12, Limited Partnership, which is the sole general partner of New Enterprise Associates 12, Limited Partnership. Peter J. Barris, M. James Barrett, Charles W. Newhall III, Ryan D. Drant, Eugene A. Trainor III, C. Richard Kramlich, Mark W. Perry, Scott D. Sandell, Forest Baskett, Charles M. Linehan, Krishna S. Kolluri and Patrick Kerins are the managers of NEA 12 GP, LLC. As a result, Messrs. Barris, Barrett, Newhall, Drant, Trainor, Kramlich, Perry, Sandell, Baskett, Linehan, Kolluri and Kerins may be considered beneficial owners of any shares deemed to be beneficially owned by New Enterprise Associates 12, Limited Partnership. Each of the aforementioned persons disclaims beneficial interest of these shares, except to the extent of his pecuniary interest therein.

*Description of Registered Securities*

We are registering issuance of us of up to 855,948 shares of our common stock upon exercise of the replacement options. We are also registering the resale of (i) the 58,987 shares of our common stock issuable upon

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exercise of the Loan Warrants, (ii) the 3,980,259 shares of our common stock issued in the August 2008 Financing Transaction and (iii) the 1,326,753 shares of our common stock issuable upon exercise of the 2008 Warrants (each as described below). In addition, in connection therewith, we have agreed to pay all expenses related to the filing of the registration statement.

### *Relationships between the Company and the Selling Stockholders*

Cherrell Hirst, Michael Spooner, and Gary Pace, each a member of our board of directors, hold replacement options.

Mr. Scopa, a member of our board of directors, is a managing member of MPM BioVentures IV LLC which has the power to exercise voting control of shares held by MPM BioVentures IV-QP L.P. and its affiliates. MPM BioVentures IV-QP L.P. and its affiliates were purchasers in the 2008 Financing Transaction and hold replacement options.

Orbis MIS- Orbis/SM Australia Equity, Warakirri Endeavour Fund, Construction and Building Union Superannuation Fund and Intech Australia Shares High Alpha Trust, which were each purchasers in the 2008 Financing Transaction, are affiliates of Orbis Global Equity Fund Limited, which beneficially holds approximately 13% of our outstanding common stock.

Asia Union Investments, which was a purchaser in the 2008 Financing Transaction, beneficially holds approximately 11% of our outstanding common stock.

Michael Aldridge, our former Chief Executive Officer, holds replacement options.

See Certain Relationships and Related Transactions, and Director Independence for further information about previous relationships between the selling stockholders, their affiliates and the Company.

### *Issuance of Warrant to General Electric Company*

On December 28, 2007, Peplin Limited, our wholly-owned subsidiary, entered into a \$15.0 million loan agreement with 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, or the Loan Agreement. In connection with the Loan Agreement, we issued a warrant to GE Capital Equity Investments, Inc. to acquire 39,325 shares of our common stock and a warrant to Oxford Finance Corporation to acquire 19,662 shares of our common stock, together referred to in this prospectus as the Loan Warrants. The Loan Warrants are immediately exercisable at an exercise price of \$15.26 per share and will expire five years after the date of issuance, or December 28, 2012.

### *Sale of Common Stock and Warrants*

On August 18, 2008, we entered into a stock subscription and registration rights agreement with several investors for the private placement of 3,980,259 shares of our common stock and warrants to purchase 1,326,753 shares of our common stock. The shares and warrants were sold as a unit, consisting of three shares of common stock and a warrant to acquire an additional share of common stock. The purchase price was \$18.14 per unit, resulting in gross proceeds to us of approximately \$24 million, prior to offering fees and expenses payable by us. The sale of the units closed on October 23, 2008. We refer to this sale transaction in this prospectus as the August 2008 Financing Transaction. The warrants issued in the August 2008 Financing Transaction are immediately exercisable, have an exercise price of \$7.86 per share and will expire five years after the date of issuance, or October 23, 2013. We refer to these warrants in this prospectus as the 2008 Warrants.



**Table of Contents****CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

We describe below transactions and series of similar transactions, since July 1, 2005, to which we and Peplin Limited, now our wholly-owned subsidiary, have been a party, in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, referred to herein as a related party transaction.

Our audit committee charter, which was adopted in July 2007, provides that our audit committee must review and approve in advance any related party transaction. In approving or rejecting a proposed related party transaction, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products, if applicable, and the impact on a director's independence. Our audit committee shall approve only those related party transactions that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our audit committee determines in the good faith exercise of its discretion. All of the transactions described below were approved by our audit committee or our board of directors.

***Purchase Agreement***

Pursuant to a purchase agreement for shares and options entered into in May 2006, by and among Peplin Limited and MPM BioVentures IV-QP L.P., MPM BioVentures IV, L.P. and MPM Asset Management Investors BV4, or collectively, MPM, Peplin Limited undertook to procure that a resolution be put to shareholders to appoint Mr. Scopa, who is a general partner 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 also elected by shareholders in June 2006. Since each respective election, Mr. Scopa and Dr. Bauer have served as directors under the terms of the constitution of Peplin Limited and no further obligations in relation to their appointments exist under the purchase agreement. We have paid MPM fees related to our capital raisings in 2006 in the amounts of \$93,292, and \$57,240 in the years ended June 30, 2006 and 2007, respectively.

***Sales of Securities***

In May 2006, Peplin Limited issued in a private placement offering an aggregate of 18,675,500 ordinary shares, or 933,775 shares of common stock after giving effect to the Reorganization, at a per share price of \$0.52, and 5,597,250 options, or 279,863 options giving effect to the Reorganization, at a per option price of \$0.68, for aggregate consideration of approximately \$30.0 million. One of our directors, Dr. Gary Pace, purchased 185,000 ordinary shares and 55,500 options in the offering, for which Peplin Limited received \$97,501.

On September 11, 2007 and October 8, 2007, Peplin Limited issued an aggregate of 22,222,222 ordinary shares, or 1,111,112 shares after giving effect to the Reorganization, for an aggregate consideration of approximately \$17.1 million. The issuance was made in a private placement to certain investors pursuant to subscription agreements with Peplin Limited, entered into on August 9, 2007, which contained customary provisions for such agreements, including representations and warranties with respect to each party, covenants designed to preserve exemption from registration under the Securities Act of 1933 and confidentiality provisions. In addition, Peplin Limited reimbursed MPM BioVentures IV LLC, an existing stockholder, \$14,700 of its legal costs incurred in connection with the transaction. Dr. Patou, a consultant who served as Interim Chief Medical Officer from June 2006 to April 2007 and again from June 2008 through August 2008, is an executive partner of MPM BioVentures IV LLC. However, Dr. Patou was not a consultant or one of our executive officers when this transaction occurred.

The purchasers of the ordinary shares included, among others, the following stockholders of Peplin Limited.

	Shares	Purchase Price(2)
Entities affiliated with MPM BioVentures IV LLC(1)	6,967,777	\$ 5,365,188
Acorn Capital	4,819,145	\$ 3,710,742
Orbis Funds	4,473,972	\$ 3,444,958
Asian Union Investments	4,215,779	\$ 3,246,150

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- (1) Mr. Scopa, a member of our board of directors, is a managing member of MPM BioVentures IV LLC, one of the MPM entities that acquired the above-listed shares.
- (2) Amounts have been converted from Australian dollars using the foreign currency exchange rate on August 9, 2007, of \$0.8542 per A\$. On August 18, 2008, we entered into a stock subscription and registration rights agreement with several investors for the private placement of 3,980,259 shares of our common stock and warrants to purchase 1,326,753 shares of our common stock. The shares and warrants were sold as a unit, consisting of three shares of common stock and one warrant. The purchase price was \$18.14 per unit, resulting in gross proceeds of approximately \$24 million, prior to offering fees and expenses payable by us. The sale of the units closed on October 23, 2008. The purchasers of the shares included, among others, the following of our stockholders.

	Units	Purchase Price
Entities affiliated with MPM BioVentures IV-QP L.P.(1)	385,885	\$ 6,999,954
Asia Union Investments	57,148	\$ 1,036,665
Entities affiliated with Orbis Funds	142,872	\$ 2,591,698
New Enterprise Associates	264,608	\$ 4,799,989

- (1) Mr. Scopa, a member of our board of directors, is a managing member of MPM BioVentures IV LLC which has the power to exercise voting control of shares held by MPM BioVentures IV-QP L.P. and its affiliates. The stock subscription agreement also requires us to register for resale the shares of common stock sold in this transaction, as well as the shares issuable upon exercise of the warrants. This prospectus forms part of the registration statement filed to satisfy that obligation.

In addition, we agreed to reimburse MPM BioVentures IV LLC, for up to \$22,500 of its legal costs incurred in connection with the transaction.

In connection with sale of the units, we also entered into a separate registration rights agreement with the investors in the August 2008 private placement, pursuant to which the investors were provided the right, subject to certain exceptions and requirements, to (i) require us to register shares of our common stock held by them on Form S-3 under the Securities Act and (ii) include any shares of our common stock held by them on a registration statement filed by us with the SEC, pursuant to which we seek to register shares of our common stock for sale to the public. This registration rights agreement was executed simultaneously with the issuance of the units. For a description of the rights provided in the registration rights agreement, see the section of this prospectus entitled "Description of Registrant's Securities to be Registered - Registration Rights."

**Acquisition of Neosil, Inc.**

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 of \$6.7 million was settled with 819,378 shares of our common stock in exchange for all the outstanding shares of Neosil. Dr. Bauer, a member of our board of directors and chief medical officer, was the chief executive officer of Neosil and a stockholder in Neosil. In addition, several entities affiliated with MPM BioVentures IV LLC, which Mr. Scopa is a managing member of, were also stockholders in Neosil. In connection with the merger, Dr. Bauer and the entities affiliated with MPM BioVentures IV LLC received zero and 519,802 shares of our common stock, respectively. This transaction closed on October 16, 2008, and the shares of common stock were issued that same day.

***Indemnification Agreements with Executive Officers and Directors***

We expect to enter into indemnification agreements with each of our executive officers and directors. These indemnification agreements require us to indemnify these individuals to the fullest extent permitted by the Delaware General Corporation Law.

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**DESCRIPTION OF CAPITAL STOCK**

**General**

Our certificate of incorporation authorizes capital stock consisting of:

10,000,000 shares of preferred stock, par value \$0.001 per share;

100,000,000 shares of common stock, par value \$0.001 per share; and

1 share of class B common stock, par value \$0.001 per share.

As of September 30, 2008, there were no shares of preferred stock or class B common stock outstanding and there were 10,341,484 shares of common stock outstanding. As of September 30, 2008, we had 92 record holders of our common stock and 3,221 holders of our CHES Depository Interests, or CDIs.

Certain provisions of our certificate of incorporation and our by-laws summarized below may be deemed to have an anti-takeover effect and may delay or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest.

**Preferred Stock**

Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the designations, powers, preferences and rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights and preferences, conversion rights, voting rights, terms of redemption and liquidation rights and preferences, any or all of which may be greater than the rights of the common stock. Accordingly, our board of directors, without stockholder approval, may issue preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may adversely affect the voting and other rights of the holders of our common stock. At present, we have no plans to issue any shares of preferred stock.

**Common Stock**

All holders of shares of common stock are entitled to the same rights and privileges. Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to receive proportionately our net assets available after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

**Class B Common Stock**

A holder of the class B common stock is entitled to the same rights and privileges as the holders of the common stock. We redeemed the class B common stock upon issuance of common stock in connection with the Reorganization.



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**Table of Contents****Warrants**

As of the date of this prospectus, warrants exercisable for a total of 1,385,740 shares of our common stock were outstanding. 58,987 of these warrants were issued in connection with the entrance of Peplin Limited, our wholly-owned subsidiary, into a loan agreement on December 28, 2007. These warrants were immediately exercisable at an exercise price of \$15.26 per share and will expire five years after the date of issuance, or December 28, 2012. The remaining 1,326,753 warrants were issued pursuant to the stock subscription and registration rights agreement, dated August 18, 2008, by and among us and the investors named therein. These warrants are immediately exercisable at an exercise price of \$7.86 per share and will expire five years after the date of issuance, or October 23, 2013. All the outstanding warrants have a conversion provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of common stock, based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. All of the outstanding warrants also contain provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits or stock combinations, reclassifications, combinations or exchanges.

**Replacement Options**

In June and July of 2006, our former parent, Peplin Limited, issued options to purchase an aggregate of 17,130,426 shares of Peplin Limited. These options were freely tradeable on the Australian Securities Exchange, or the ASX, and were exercisable for AU\$0.84 per share. In October 2007, Peplin Limited was reorganized into us pursuant to a Scheme of Arrangement. We refer to this transaction as the Reorganization. On October 16, 2007, pursuant to the Reorganization, we issued the shareholders of Peplin Limited an aggregate of 10,341,484 shares of our common stock, representing one share of our common stock for every 20 shares of Peplin Limited that were issued and outstanding. Additionally, we cancelled each of the outstanding options to acquire shares of Peplin Limited that were listed on the ASX, and issued uncertificated replacement options representing the right to acquire 855,948 shares of our common stock calculated using the same 1-for-20 exchange ratio. The replacement options have an exercise price of \$13.05 per share and expire on June 30, 2010. The shares and the replacement options issued in the Reorganization were exempt from registration as securities issued pursuant to Section 3(a)(10) of the Securities Act given that the terms and conditions of the issuance and exchange were approved, after a hearing upon the fairness of the terms and conditions, by a court expressly authorized by law to grant such approval.

**Registration Rights**

As of October 23, 2008, the holders of an aggregate of 6,185,377 shares of our common stock, which includes 1,385,740 shares of common stock issuable upon the exercise of warrants, are entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act of 1933, as amended, or the Securities Act. The registration of shares of our common stock as a result of the registration rights being exercised would enable the holders to trade these shares without restriction under the Securities Act when the registration statement is declared effective. Generally, we will be required to pay all expenses related to any registration effected pursuant to the exercise of the registration rights described below, other than underwriting commissions and discounts.

***Reorganization Agreement***

On October 16, 2008, pursuant to the Agreement and Plan of Reorganization, dated June 9, 2008, by and among us, West Acquisitions Corp., Neosil Inc. and Nicolas J. Simon III, or the Reorganization Agreement, we issued 819,378 shares of our common stock. Under the Reorganization Agreement, we are obligated to use commercially reasonable efforts to prepare and file a registration statement registering the resale of the shares of common stock on or prior to December 31, 2008. We are also obligated to use commercially reasonable efforts to have such registration statement declared effective as promptly as practicable after filing.

***Stock Subscription Agreement dated August 18, 2008***

Pursuant to the stock subscription and registration rights agreement, dated August 18, 2008, among us and certain investors, or the Stock Subscription Agreement, we issued 5,307,012 shares, which includes 1,326,753 shares of common stock issuable upon the exercise of warrants. We are required to use commercially reasonable efforts to prepare and file a registration statement on Form S-1 for the registration of the securities issued under the Stock Subscription Agreement prior to November 30, 2008. The Stock Subscription Agreement also requires us to

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use commercially reasonable efforts to have such registration statement declared effective prior to March 30, 2009, and to keep the registration statement effective until all the securities may be sold in compliance with Rule 144 of the Securities Act. If we fail to meet the November 30, 2008 or March 30, 2009 deadlines, we are obligated to make *pro rata* payments to each investor that continues to hold registrable securities in an amount equal to 1.0% per month of the aggregate purchase price paid by such investor for each unit then held by such investor for each following thirty calendar day period. Our liability is limited to 12.0% of the aggregate purchase price paid for all common stock and warrants acquired by such investor.

In connection with a \$15 million loan agreement with General Electric Capital Corporation dated December 28, 2007, we issued GE Capital Equity Investments, Inc. and Oxford Finance Corporation warrants to purchase 39,325 and 19,662 shares of common stock, respectively. We entered into registration rights agreements with GE Capital Equity Investments, Inc. and Oxford Finance Corporation containing substantially the same terms as those set forth in the preceding paragraph. If we fail to meet the November 30, 2008 or March 30, 2009 deadlines, we are obligated to make *pro rata* payments to each investor that continues to hold registrable securities in an amount equal to 1.0% per month of the aggregate exercise price paid or to be paid by each investor for each warrant share or warrant share issuable upon exercise of a warrant for each following thirty calendar day period. Our liability is limited to 12.0% of the aggregate exercise price paid or payable for all warrant shares acquired by such investor.

### ***Registration Rights Agreement dated October 23, 2008***

Pursuant to a registration rights agreements, dated October 23, 2008 by and among us and certain investors, if at any time after we become entitled under the Securities Act to register our shares on Form S-3, or any successor form adopted under the Securities Act and permitting the resale of restricted securities on a delayed or continuous basis, a holder of the registrable securities requests in writing that we effect a registration that has an anticipated offering aggregate price, net of selling expenses, of at least \$5,000,000, we may be required to register their shares; provided, however, that if such registration would be seriously detrimental to us or our stockholders, we may defer the registration for up to 90 days.

Each time we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities under the registration rights agreement will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

The registration rights granted pursuant to the registration rights agreement terminate upon the earlier of five years after completion of the completion of an initial public offering by us.

### **Anti-Takeover Effects of Certain Provisions**

#### ***Section 203 of the Delaware General Corporation Law***

In general, Section 203 of the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the voting stock owned by the interested stockholder) those shares owned by persons who are directors and also officers, and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or

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the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines "business combination" to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

in general, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to certain exceptions;

any transaction involving the corporation which has the effect of increasing the proportionate share of any class or series of its capital stock owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### ***Classified Board of Directors***

Our certificate of incorporation divides our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our by-laws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 66 2/3% or more of our outstanding shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and by-laws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by the affirmative vote of a majority of our directors then in office. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors and fill vacancies could make it more difficult for a third-party to acquire, or discourage a third-party from seeking to acquire, control of us.

### ***No Cumulative Voting***

Our certificate of incorporation provides that our stockholders are not permitted to cumulate their votes for the election of directors.

### ***Stockholder Action by Written Consent***

Our certificate of incorporation and our by-laws allow any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders to be taken by written consent in lieu of a meeting.

### ***Special Meetings of Stockholders***

Our by-laws also provide that, except as otherwise required by law, special meetings of the stockholders may only be called by our board of directors. These provisions may make it difficult for stockholders to take action that has not been approved by our board of directors or the chairman of our board.

### ***Advance Notice Requirements for Stockholder Proposals and Director Nominations***

## Edgar Filing: PEPLIN INC - Form 424B3

In addition, our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the



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record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

### ***Preferred Stock***

Pursuant to the terms of our certificate of incorporation, we are authorized to issue up to 10,000,000 shares of preferred stock. Our board of directors are authorized, subject to any limitations prescribed by law, without further stockholder approval, to issue such shares of preferred stock in one or more series. Each such series of preferred stock shall have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by our board of directors. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or of discouraging a third-party from attempting to acquire, a majority of our outstanding common stock.

### ***Amendment of Certificate of Incorporation or By-laws***

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our by-laws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders of at least 66 2/3% of the votes which all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 66 2/3% of the votes which all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation and by-laws described in the prior two paragraphs.

### **CHESSE Depository Interests**

Prior to the consummation of the Reorganization, the ordinary shares of Peplin Limited were listed on the ASX. Currently, the beneficial ownership of our common stock is listed on the ASX in the form of CHESSE Depository Interests, or CDIs, under the ASX trading code PLI. CDIs are units of beneficial ownership in our shares of common stock held by CHESSE Depository Nominees Pty Limited, or CDN, a wholly-owned subsidiary of ASX. The CDIs entitle holders to dividends, if any, and other rights economically equivalent to our shares of common stock on a 1-for-20 basis, including the right to attend stockholders' meetings. The CDIs are convertible at the option of the holders into our shares of our common stock on a 1-for-20 basis. CDN, as the stockholder of record, will vote the underlying shares in accordance with the directions of the CDI holders.

### **ASX Listing Rules**

The ASX Listing Rules prohibit us from acquiring a substantial asset from, or disposing of a substantial asset to, one of our directors without stockholder approval. In addition, subject to certain exceptions, the ASX Listing Rules prohibit us from issuing shares to a director without stockholder approval.

In addition, under the listing rules of the ASX, the maximum fees payable to a directors may not increase without prior approval from stockholders at a general meeting. The directors will seek approval from time to time in relation to fees as they think appropriate.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The registrar for our CDIs is Computershare.

### **ASX Listing**

Currently, our CDIs trade on the ASX under the symbol PLI.

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**SHARES ELIGIBLE FOR FUTURE SALE**

Upon completion of this offering, we will have outstanding an aggregate of approximately 15,141,129 shares of common stock based upon our shares outstanding as of September 30, 2008. Of these shares outstanding, all of the shares that may be sold by the selling stockholders pursuant to this prospectus will be freely tradeable without restriction under the Securities Act. Additionally, 855,948 shares issuable upon exercise of our outstanding replacement options will be, upon issuance, freely tradeable without restriction under the Securities Act unless they are held by our affiliates as such term is defined in Rule 144 of the Securities Act. An additional 10,341,484 shares represent shares of our common stock that were issued to former Peplin Limited stockholders in connection with the Reorganization pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act. These securities will also be freely tradeable, except for securities held by persons who are deemed to be affiliates of Peplin Limited prior to completion of the Reorganization or affiliates of us following the Reorganization. The 1,748,022 shares of our common stock issued in the Reorganization and held by affiliates are available for public sale only if registered under the Securities Act or sold in compliance with Rule 144 of the Securities Act as currently in effect.

**Rule 144**

In general, under Rule 144 of the Securities Act, once we have been subject to public company reporting requirements for at least 90 days (which will occur on January 28, 2009), a person (or persons whose shares are required to be aggregated) who has beneficially owned restricted securities for at least six months, and who is our affiliate at the time of, or at any time during the 90 days preceding, a sale, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

one percent of the number of common shares then outstanding, which currently equals approximately 151,411 shares (assuming no exercise outstanding options or warrants); or

the average weekly trading volume of our common shares on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of restricted shares by our affiliates under Rule 144 of the Securities Act are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us.

For a person who has not been deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, sales of our securities held longer than six months, including the holding period of any prior owner other than an affiliate, but less than one year, will be entitled to sell those shares subject only to the current public information requirement. Rule 144 also provides that affiliates that sell our common shares that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

**Rule 701**

In general, under Rule 701 as currently in effect, any of our employees, consultants or advisors who purchase shares from us in connection with a compensatory stock or option plan or other written agreement in a transaction before the effective date of this offering that was completed in reliance on Rule 701 and complied with the requirements of Rule 701 will be eligible to resell such shares 90 days after the effective date of our form 10 registration statement in reliance on Rule 144, but without compliance with certain restrictions, including the holding period, contained in Rule 144.

**Stock Options and Restricted Shares**

As of September 30, 2008, options to purchase a total of 1,735,468 shares of our common stock were outstanding, of which 1,388,255 were exercisable. An additional 679,467 shares of common stock were available for future option grants under our 2007 Incentive Award Plan. We have filed a registration statement on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our option plan. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the Securities and Exchange Commission. In addition, we intend to file one or



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more registration statements under the Securities Act to register the resale of 819,378 shares of our common stock that were issued in connection with our acquisition of Neosil, Inc. Accordingly, shares registered these such registration statements will be available for sale in the open market, unless such shares are subject to vesting restrictions with us.

**Holders**

As of September 30, 2008, there were no shares of preferred stock or class B common stock outstanding, and there were 10,341,484 shares of common stock outstanding. As of September 30, 2008, we had 92 record holders of our common stock and 3,221 holders of our CHESSE Deposit Interests.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all of our future earnings to finance the growth and development of our business. Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend upon our results of operations, financial condition, current and anticipated cash needs, contractual restrictions, restrictions imposed by applicable law, operating results, capital requirements and such other factors as our board of directors deems relevant.

**Securities Authorized for Issuance**

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights(a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights(b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)(c))</b>
Plans approved by stockholders	820,533	\$ 14.59	679,467
Plans not approved by stockholders			
<b>Total</b>	<b>820,533</b>	<b>\$ 14.59</b>	<b>679,467</b>

(a) Represents the number of securities to be issued upon exercise of outstanding options under our 2007 Incentive Award Plan.

(b) Represents the weighted-average exercise price of outstanding options under our 2007 Incentive Award Plan.

(c) Represents the number of securities remaining available for issuance under our 2007 Incentive Award Plan, excluding securities to be issued upon exercise of outstanding options under the 2007 Incentive Award Plan.

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**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR  
COMMON STOCK**

The following is a general discussion of the material United States federal income tax consequences relating to the purchase, ownership and disposition of our common stock by a non-U.S. holder, but is not a complete analysis of all the potential tax consequences relating thereto. For the purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock (other than a partnership) that for U.S. federal income tax purposes is not a United States person. For purposes of this discussion, the term United States person means:

an individual citizen or resident of the United States;

a corporation or a partnership (or other entity taxable as a corporation or a partnership) created or organized in the United States or under the laws of the United States or any state thereof or the District of Columbia;

an estate whose income is subject to United States federal income tax regardless of its source; or

a trust (x) if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more United States persons have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a United States person under applicable U.S. Treasury regulations.

If a partnership (or an entity treated as a partnership for United States federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will generally depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships which hold our common stock and partners in such partnerships should consult their tax advisors.

This discussion does not address all aspects of United States federal income taxation that may be relevant in light of a non-U.S. holder's special tax status or special circumstances. Former citizens or residents of the United States, insurance companies, tax-exempt organizations, partnerships or other pass-through entities for United States federal income tax purposes, dealers in securities, banks or other financial institutions, controlled foreign corporations, passive foreign investment companies and investors that hold our common stock as part of a hedge, straddle or conversion transaction are among those categories of potential investors that are subject to special rules not covered in this discussion. This discussion does not address the tax consequences to non-U.S. holders that do not hold our common stock as a capital asset for United States federal income tax purposes (generally, property held for investment). This discussion also does not address any tax consequences arising under the laws of any state, local or non-United States taxing jurisdiction. Furthermore, the following discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, and United States Treasury regulations and administrative and judicial interpretations thereof, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or the IRS, with respect to the matters discussed below, and there can be no assurance that the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, or that any such contrary position would not be sustained by a court. Accordingly, each non-U.S. holder should consult its tax advisors regarding the United States federal, state, local and non-United States income and other tax consequences of acquiring, holding and disposing of our common stock.

**PROSPECTIVE INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.**

**Dividends**

Distributions on our common stock, if any, generally will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under



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United States federal income tax principles. Amounts not treated as dividends for United States federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's adjusted tax basis in the common stock, but not below zero, and then the excess, if any, will be treated as gain from the sale of the common stock.

Amounts treated as dividends paid to a non-U.S. holder generally will be subject to withholding of United States federal income tax either at a rate of 30% of the gross amount of the dividends or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN or other successor form certifying qualification for the reduced rate.

Dividends received by a non-U.S. holder that are effectively connected with a United States trade or business conducted by the non-U.S. holder (and if required by an applicable income tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States) are exempt from such withholding tax. In order to obtain this exemption, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8ECI or other successor form properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are generally taxed at the same graduated rates applicable to United States persons, net of allowable deductions and credits, subject to an applicable income tax treaty providing otherwise.

In addition to the graduated tax described above, dividends received by a corporate non-U.S. holder that are effectively connected with a United States trade or business of such holder may also be subject to a branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable tax treaty) on its effectively connected earnings and profits for the taxable year.

A non-U.S. holder may obtain a refund of any excess amounts withheld if an appropriate claim for refund is filed timely with the IRS. If a non-U.S. holder holds our common stock through a foreign partnership or a foreign intermediary, the foreign partnership or foreign intermediary will also be required to comply with additional certification requirements.

### **Gain on Disposition of Common Stock**

A non-U.S. holder generally will not be subject to United States federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

the gain is effectively connected with a United States trade or business of the non-U.S. holder or, if required by an applicable tax treaty, is attributable to a permanent establishment maintained by such non-U.S. holder in the United States;

the non-U.S. holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year in which the sale or other disposition occurs and other conditions are met; or

our common stock constitutes a United States real property interest by reason of our status as a United States real property holding corporation, or USRPHC, for United States federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the holder's holding period for our common stock.

We believe that we are not currently and do not anticipate becoming a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as a United States real property interest only if the non-U.S. holder actually or constructively held more than 5 percent of such regularly traded common stock during the applicable period.

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Unless an applicable tax treaty provides otherwise, gain described in the first bullet point above will be subject to the United States federal income tax imposed on net income on the same basis that applies to United States persons generally and, for corporate holders under certain circumstances, the branch profits tax, but will generally not be subject to withholding tax. Gain described in the second bullet point above (which may be offset by United States source capital losses) will be subject to a flat 30% United States federal income tax. Non-U.S. holders should consult any applicable income tax treaties that may provide for different rules.

### **Backup Withholding and Information Reporting**

Generally, we must report annually to the IRS the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld, together with other information. A similar report is sent to the holder. These information reporting requirements apply even if withholding was not required because the dividends were effectively connected dividends or withholding was reduced or eliminated by an applicable tax treaty. Pursuant to tax treaties or other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Backup withholding (currently at a rate of 28%) will generally not apply to payments of dividends made by us or our paying agents, in their capacities as such, to a non-U.S. holder if the holder has provided certification that it is not a United States person (on the forms described above) or has otherwise established an exemption, provided we or the paying agent have no actual knowledge or reason to know that the beneficial owner is a United States person.

Payments of the proceeds from a disposition effected outside the United States by a non-U.S. holder made by or through a foreign office of a broker generally will not be subject to information reporting or backup withholding. However, information reporting (but generally not backup withholding) will apply to such a payment if the broker is a United States person, a controlled foreign corporation for United States federal income tax purposes, a foreign person 50% or more of whose gross income is effectively connected with a United States trade or business for a specified three year period, or a foreign partnership if (i) at any time during its tax year, one or more of its partners are United States persons who, in the aggregate, hold more than 50 percent of the income or capital interest in such partnership or (ii) at any time during its tax year, it is engaged in the conduct of a trade or business in the United States, unless an exemption is otherwise established, provided that the broker has no knowledge or reason to know that the beneficial owner is a United States person.

Payment of the proceeds from a disposition by a non-U.S. holder of common stock made by or through the United States office of a broker is generally subject to information reporting and backup withholding unless the non-U.S. holder certifies as to its non-U.S. holder status under penalties of perjury or otherwise establishes an exemption from information reporting and backup withholding, provided that the broker has no knowledge or reason to know that the beneficial owner is a United States person.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's United States federal income tax liability provided the required information is timely furnished to the IRS.



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**PLAN OF DISTRIBUTION**

The selling stockholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their Resale Securities or their interests in the shares of common stock issuable upon exercise of the warrants or options on any stock exchange, market or trading facility on which the shares are traded or in private transactions. There is currently no publicly traded market for our common stock in the United States. Our common stock is publicly traded on the ASX. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may use one or more of the following methods when disposing of the Resale Securities or interests therein:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

through brokers, dealers or underwriters that may act solely as agents;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

through the writing or settlement of options or other hedging transactions entered into after the effective date of the registration statement of which this prospectus is a part, whether through an options exchange or otherwise;

broker-dealers may agree with the selling stockholders to sell a specified number of the Resale Securities at a stipulated price per share;

the distribution of the Resale Securities to partners, members or security holders of the selling stockholders;

a combination of any such methods of disposition; and

any other method permitted pursuant to applicable law.

The selling stockholders may also sell the Resale Securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

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Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the Resale Securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Resale Securities from time to time under this prospectus, or under a supplement or amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

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Upon being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of Resale Securities through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the type and number of Resale Securities involved, (iii) the price at which such Resale Securities were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out in this prospectus, and (vi) other facts material to the transaction.

The selling stockholders also may transfer Resale Securities in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of the Resale Securities, the selling stockholders may enter into hedging transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions, which may in turn engage in short sales of the Resale Securities in the course of hedging the positions they assume. The selling stockholders may also sell Resale Securities short after the effective date of the registration statement of which this prospectus is a part and deliver these Resale Securities to close out their short positions, or loan or pledge the Resale Securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

From time to time the selling stockholders may solicit offers to purchase securities directly from the public, designate agents to solicit offers to purchase securities from the public on their behalf, sell securities to one or more dealers acting as principals, or sell securities to one or more underwriters, who would purchase the Resale Securities as principal for resale to the public, either on a firm-commitment or best-efforts basis. If the selling stockholders sell Resale Securities to an underwriter, we and the selling stockholders may execute an underwriting agreement with them at the time of sale. Any broker-dealers, agents or underwriters that participate with the selling stockholders in the distribution of the common stock may be deemed to be underwriters within the meaning of the Securities Act, in which event any commissions received by these broker-dealers, agents or underwriters may be deemed to be underwriting commissions or discounts under the Securities Act.

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. We will, however, receive the proceeds from any replacement options, 2008 Warrants, or Loan Warrants exercised for cash.

We are required to pay all fees and expenses incident to the registration of the Resale Securities. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act or otherwise.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the date on which the shares of common stock subject to registration rights may be sold without any volume limitations pursuant to Rule 144 of the Securities Act. Each selling stockholder may sell all, some or none of the Resale Securities offered by this prospectus.

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**LEGAL MATTERS**

The validity of the common stock being offered hereby will be passed upon for us by Latham & Watkins LLP, Costa Mesa, California.

**EXPERTS**

Ernst & Young, independent registered public accounting firm, has audited our consolidated financial statements at June 30, 2008 and 2007, and for each of the three years in the period ended June 30, 2008 as set forth in their report. We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

This prospectus is part of a registration statement on Form S-1 that we have filed with the Securities and Exchange Commission under the Securities Act covering the securities offered by the selling stockholders. As permitted by the rules and regulations of the Securities and Exchange Commission, this prospectus omits certain information contained in the registration statement. For further information with respect to us and our securities, you should refer to the registration statement and to its exhibits and schedules. We make reference in this prospectus to certain of our contracts, agreements and other documents that are filed as exhibits to the registration statement. For additional information regarding those contracts, agreements and other documents, please see the exhibits attached to this prospectus.

You can read and copy the registration statement and the exhibits and schedules filed with the registration statement or any reports, statements or other information we have filed or file, at the public reference facilities maintained by the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents from such offices upon payment of the prescribed fees. You may call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference room. You may also request copies of the documents upon payment of a duplicating fee, by writing to the Securities and Exchange Commission. In addition, the Securities and Exchange Commission maintains a web site that contains reports and other information regarding registrants that file electronically with the Securities and Exchange Commission, which you can access at <http://www.sec.gov>.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Peplin, Inc.

We have audited the accompanying consolidated balance sheets of Peplin, Inc. (a development stage company) as of June 30, 2007 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, 2008 and for the period from inception (December 7, 1999) to June 30, 2008. 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 audit 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. at June 30, 2007 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, 2008, and for the period from inception (December 7, 1999) to June 30, 2008, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young

Brisbane, Australia

August 22, 2008

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(a development stage enterprise)

**CONSOLIDATED BALANCE SHEETS**

	June 30,	
	2007	2008
<b>Assets:</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 20,245,960	\$ 25,230,533
Grant income receivable	17,922	169,776
Interest receivable	118,165	131,443
Prepaid expenses	492,124	778,923
Deferred costs	529,148	4,655,836
Other current assets	56,580	982,400
<b>Total current assets</b>	<b>21,459,899</b>	<b>31,948,911</b>
<b>Non-current assets:</b>		
Restricted cash	312,364	390,698
Lease deposits	162,193	176,170
Plant and equipment - net	2,154,034	2,824,111
Other non-current assets		629,206
<b>Total non-current assets</b>	<b>2,628,591</b>	<b>4,020,185</b>
<b>Total assets</b>	<b>\$ 24,088,490</b>	<b>\$ 35,969,096</b>
<b>Liabilities and stockholders' equity:</b>		
<b>Current liabilities:</b>		
Trade accounts payable	\$ 323,533	\$ 1,282,542
Accrued research and development	3,137,403	2,024,704
Accrued employee benefits and payroll taxes	489,947	779,621
Notes payable		5,163,171
Other accrued expenses	298,337	1,168,397
<b>Total current liabilities</b>	<b>4,249,220</b>	<b>10,418,435</b>
<b>Non-current liabilities:</b>		
Accrued employee benefits and payroll taxes	42,178	48,491
Asset retirement obligation	59,963	74,504
Notes payable		8,612,934
Debt completion fee payable		600,000
<b>Total liabilities</b>	<b>4,351,361</b>	<b>19,754,364</b>

**Commitments and contingencies (Note 9)****Stockholders' equity:**

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Preferred stock, \$0.001 par value: 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2007 and June 30, 2008		
Common stock, \$0.001 par value: 100,000,000 shares authorized; 9,229,676, and 10,341,484 issued and outstanding at June 30, 2007, and June 30, 2008, respectively <sup>(1)</sup>	61,519,129	80,744,288
Class B Common stock, \$0.001 par value: 1 share authorized, no shares issued and outstanding at June 30, 2007, and June 30, 2008		
Deficit accumulated during development stage	(46,106,595)	(72,062,843)
Accumulated other comprehensive income	4,324,595	7,533,287
<b>Total stockholders equity</b>	19,737,129	16,214,732
<b>Total liabilities and stockholders equity</b>	\$ 24,088,490	\$ 35,969,096

<sup>(1)</sup> Common stock has been retroactively adjusted to reflect the 20:1 reverse stock split. See Note 1. See accompanying notes to financial statements.



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PEPLIN, INC.

(a development stage enterprise)

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended June 30,			For the period from inception (December 7, 1999) to June 30, 2008
	2006	2007	2008	
<b>License fee revenues</b>	\$	\$	\$	\$ 5,770,510
<b>Cost of operations:</b>				
Research and development	9,265,161	18,237,691	19,578,667	65,856,518
General and administrative	2,069,689	4,112,192	8,088,970	19,860,406
<b>Total cost of operations</b>	<b>11,334,850</b>	<b>22,349,883</b>	<b>27,667,637</b>	<b>85,716,924</b>
<b>Loss from operations</b>	<b>(11,334,850)</b>	<b>(22,349,883)</b>	<b>(27,667,637)</b>	<b>(79,946,414)</b>
<b>Other income (expenses):</b>				
Interest income	548,246	1,537,676	1,540,748	4,585,030
Interest expense			(1,219,221)	(1,239,355)
Grant income	446,357	238,404	1,369,013	4,319,134
Other income		10,446	41,435	239,348
<b>Total other income</b>	<b>994,603</b>	<b>1,786,526</b>	<b>1,731,975</b>	<b>7,904,157</b>
<b>Net loss before income tax expense</b>	<b>(10,340,247)</b>	<b>(20,563,357)</b>	<b>(25,935,662)</b>	<b>(72,042,257)</b>
<b>Income tax expense</b>			(20,586)	(20,586)
<b>Net loss</b>	<b>\$ (10,340,247)</b>	<b>\$ (20,563,357)</b>	<b>\$ (25,956,248)</b>	<b>\$ (72,062,843)</b>
<b>Net loss per share basic and diluted<sup>(1)</sup></b>	<b>\$ (1.74)</b>	<b>\$ (2.31)</b>	<b>\$ (2.57)</b>	
<b>Weighted average common stock outstanding used in calculation of net loss per share basic and diluted<sup>(1)</sup></b>	<b>5,946,463</b>	<b>8,902,396</b>	<b>10,096,957</b>	

(1) Common stock has been retroactively adjusted to reflect the 20:1 reverse stock split. See Note 1  
See accompanying notes to financial statements.



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PEPLIN, INC.

(a development stage enterprise)

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)**

	Number of shares of common stock <sup>(1)</sup>	Amount	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
<b>Balance at inception (December 7, 1999)</b>					
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 o					