PEPLIN INC
Form S-1
August 09, 2007

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As filed with the Securities and Exchange Commission on August 9, 2007
Registration No. 333-

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

Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Peplin, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**26-0641830**
(State of Incorporation)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

6475 Christie Avenue
Emeryville, CA 94608
(510) 653-9700
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Michael D.A. Aldridge
Chief Executive Officer
6475 Christie Avenue
Emeryville, CA 94608
(510) 653-9700
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Patrick T. Seaver	**David J. Saul**
B. Shayne Kennedy	**Gavin T. McCraley**
Latham & Watkins LLP	**Wilson Sonsini Goodrich & Rosati, P.C.**
650 Town Center Drive, 20th Floor	**650 Page Mill Road**
Costa Mesa, CA 92626-1925	**Palo Alto, CA 94304-1050**
(714) 540-1235	**(650) 493-9300**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee(1)
Common Stock, par value $0.001 per share	$75,000,000	$2,302.50

(1) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission acting pursuant to said section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion

PROSPECTUS Preliminary Prospectus dated August 9, 2007

Shares

Common Stock

This is the initial public offering of our common stock. We are offering shares of common stock.

Currently, no public market exists for the shares of our common stock in the United States. The ordinary shares of our parent, Peplin Limited, are currently listed on the Australian Securities Exchange under the symbol PEP. Prior to the completion of this offering, we intend to acquire all of the outstanding ordinary shares of Peplin Limited as part of a reorganization in exchange for the issuance of shares of our common stock on a 1-for-20 basis. Following the exchange, we expect that our common stock will be listed on the Australian Securities Exchange under the symbol PLI in the form of CHESS Depository Interests that will represent 1/20th of a share of our common stock. We intend to apply to have our common stock also listed on the NASDAQ Global Market under the symbol PLIN after the completion of this offering. On , 2007, the closing price of the CHESS Depository Interests representing our common stock on the Australian Securities Exchange was A$ per interest, representing a price of $ per share of common stock, assuming a foreign currency exchange rate of on that date.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 9 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also purchase up to an additional shares of common stock from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover overallotments.

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 shares of common stock will be ready for delivery on or about , 2007.

Merrill Lynch & Co.

Cowen and Company

Thomas Weisel Partners LLC

Leerink Swann & Company

Wilson HTM

The date of this prospectus is , 2007.

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You should rely only on the information contained in this prospectus or any future free writing prospectus authorized by us. We have not, and the underwriters have not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus or in any free writing prospectus authorized by us. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock 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 common stock. Our business, prospects, financial condition and results of operations may have changed since that date.

For investors outside the United States and Australia: neither we nor any of the underwriters 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.

Neither this prospectus, nor any other disclosure document in relation to shares of our common stock has been, or needs to be, lodged with the Australian Securities & Investments Commission. This prospectus is not a Prospectus under Chapter 6D of the Australian Corporations Act 2001, or the Corporations Act. Any offer of shares of our common stock in Australia is made only to persons to whom it is lawful to offer shares of our common stock without disclosure under one or more of the exemptions set out in section 708 of the Corporations Act, or an Exempt Person. By accepting this prospectus, an offeree represents that the offeree is an Exempt Person. No shares of our common stock will be issued or sold in circumstances that would require the giving of a Prospectus under Chapter 6D of the Corporations Act.

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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 Limited, an Australian public company, appearing elsewhere in this 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, which is a new class of compound derived from the sap of *Euphorbia peplus*, or *E. peplus*, a rapidly growing, readily-available plant, commonly referred to as petty spurge or radium weed. *E. peplus* has a long history of traditional use for a variety of conditions, including the topical self-treatment of various skin disorders, including skin cancer and pre-cancerous skin lesions. Our lead product candidate is a patient-applied topical gel containing a compound the use of which we have patented for the treatment of actinic keratosis, or AK. This product candidate is currently in Phase IIb clinical trials and is referred to as PEP005 Topical for 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. If left untreated, AK lesions may progress to a form of skin cancer called squamous cell carcinoma, or SCC. We believe that PEP005 Topical 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 a compound the use of which we have patented 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 Topical for BCC. BCC is the most commonly occurring cancerous lesion and can present 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 Topical for BCC is at an earlier stage than that of PEP005 Topical 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, two-to-three day application regimen that would be applied in the physician s office by the physician or a clinician.

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 our lead product candidate, PEP005 Topical for AK, in off-face applications. We believe that the results of this trial, which we call PEP005-006, suggest that a single application of PEP005 Topical for AK, each day for two or three consecutive days, may present a favorable safety profile and be well tolerated. In addition, the trial demonstrated a statistically significant and clinically meaningful lesion clearance by all measures evaluated and at all doses studied.

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, particularly in fair skinned people and 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. If left untreated, AK lesions may progress to a form of skin cancer called squamous cell carcinoma, or SCC. The treatment of AK lesions is the

most common dermatologic procedure performed in the out-patient setting. The Lewin Group, Inc. estimates that the total direct cost for AK in the United States was $1.2 billion in 2004, and in 2002 there were approximately 8.2 million office visits for the treatment of AK, with a cost to the U.S. healthcare system of approximately $1.2 billion. The Lewin Group also estimated that there were 58 million people in the United States living with AK in 2004.

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

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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 in two forms, nodular BCC and superficial BCC. SCC and BCC, together, are often referred to as non-melanoma skin cancers. The Lewin Group estimates that there were 1.2 million individuals with non-melanoma skin cancer in the United States, with treatment costs to the U.S. healthcare system of $1.4 billion in 2004. Estimates suggest that the incidence of non-melanoma skin cancer increased an average of 3% to 8% per year over the period from the 1960 s to the 1990 s.

Our Product Candidates

PEP005 Topical for AK

We recently completed our PEP005-006 Phase IIb clinical trial of our PEP005 Topical for AK as a field-directed therapy for non-facial AK lesions, including lesions on the scalp. Preliminary results from the trial of 222 patients suggest that PEP005 Topical for AK 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 Topical for AK 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 cessation of treatment. The trial evaluated three efficacy measures based on various clearance rates. On the primary efficacy measure, 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 complete AK clearance and baseline AK clearance rate. In the highest dose group the complete AK clearance rate and baseline AK clearance rate were 54% and 58%, respectively, and in the lowest dose group were 40% and 42%, respectively. We must successfully complete additional trials before we can seek regulatory approval to commercialize this product candidate.

As compared with other treatment alternatives, we believe that PEP005 Topical 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 unique 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.

AK is predominantly treated using either cryotherapy alone, cryotherapy in combination with topical agents or topical agents alone. We believe PEP005 Topical for AK has the potential to expand the market for topical agents used in combination with cryotherapy.

Subject to input from the FDA we anticipate beginning our Phase III trials of PEP005 Topical for AK, with either separate or combined trials for facial or non-facial applications, in the first calendar quarter of 2008 and filing our new drug application, or NDA, with the FDA by 2009, assuming completion of our Phase III clinical program.

PEP005 Topical for BCC

The results from our most recent PEP005-003 Phase IIa clinical trial of PEP005 Topical for BCC, suggest that this drug candidate presents a favorable safety profile and is well tolerated. Further, a statistically significant portion of superficial BCC tumors in the 60 patients studied were cleared with just two applications of 0.05% PEP005 Topical for BCC. We intend to develop PEP005 Topical for BCC as an in-office, physician-applied treatment procedure for superficial BCC tumors. We are presently conducting a further Phase II trial of PEP005-009, a dose escalation clinical trial in which we are increasing the dosage of PEP005 Topical for

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BCC to establish the maximum tolerated doses when administered as a single application and when administered as two applications one week apart. We are also evaluating the tumor clearance rate at the maximum tolerated doses. 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 Topical for BCC until at least 2010.

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

Our Strategy

Our objective is to build a specialty pharmaceutical company focused on the development and commercialization of products for selected medical dermatology markets in the United States, Australia and New Zealand. Key aspects of our strategy include:

- successfully developing PEP005 Topical for AK;
- successfully developing PEP005 Topical for BCC and pursuing additional indications;
- driving the adoption of our products through a direct sales and marketing effort; and
- acquiring or in-licensing complementary drug candidates within our area of commercial focus.

Commercialization

We own the rights to develop and commercialize our products on a global basis. We plan to develop a direct sales and marketing organization to commercialize and market PEP005 Topical for AK to the dermatology community if it receives regulatory approval. Initially, we anticipate that Peplin 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.

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. In particular, you should consider the following risks, which are discussed more fully in Risk Factors beginning on page 9:

- 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, 2006 and the nine months ended March 31, 2007 were approximately $10.3 million and $14.2 million, respectively. As of March 31, 2007, we had an accumulated deficit of approximately $39.7 million.
- We are dependent on the success of our lead product candidate PEP005 Topical for AK, which is in an early stage of development, and we cannot give any assurance that it will be successfully commercialized for both facial and non-facial applications.

We rely on third parties to manufacture our products, conduct preclinical pharmacology and toxicology research and development, and conduct clinical trials on our products. Due to our reliance on third parties, we are unable to directly control the timing, conduct and expense of these activities.

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.

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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*. Information contained on our website is not a prospectus and does not constitute part of this prospectus.

Following the Reorganization, we will operate primarily through two wholly-owned subsidiaries, Peplin Operations Pty Ltd, which is responsible for worldwide development, and Peplin Operations USA, Inc., which provides developmental management services and engages in U.S. commercial activities. Other subsidiaries include: Peplin Research Pty Ltd, Peplin Unit Trust and Peplin Biolipids Pty Ltd, which collectively hold various aspects of our intellectual property.

The Reorganization

We were formed for the purpose of reorganizing our parent company, Peplin Limited, into the United States. Prior to the closing of this offering, we intend to acquire all the outstanding ordinary shares of Peplin Limited pursuant to a Scheme of Arrangement that must be approved by the Federal Court of Australia and by more than 75% in voting interest and 50% in number of Peplin Limited s shareholders present and voting at the meeting of shareholders anticipated to be completed in October 2007. We refer to this transaction throughout this prospectus as the Reorganization. Pursuant to the Reorganization we intend to issue the shareholders of Peplin Limited one share of our common stock for every 20 ordinary shares of Peplin Limited that are issued and outstanding. Additionally, we intend to cancel each of the outstanding options to acquire ordinary shares of Peplin Limited, including those that are currently listed on the Australian Securities Exchange, or ASX, and to issue replacement options representing the right to acquire shares of our common stock on the same 1-for-20 basis. Prior to the closing of the Reorganization, we have no business or operations and following the closing of the Reorganization, our business and operations will consist solely of the business and operations of Peplin Limited.

As a result, unless the context otherwise states, references throughout this prospectus to we, us, our, Peplin or the company refer to the business of Peplin Limited and its subsidiaries for all periods prior to the consummation of the Reorganization, and to the business of Peplin, Inc. and its subsidiaries (including Peplin Limited) for all periods subsequent to the consummation of the Reorganization.

The ordinary shares of Peplin Limited currently trade on the ASX under the symbol PEP. Following the Reorganization, we intend to list the beneficial ownership of our common stock on the ASX under the symbol PLI in the form of CHESS Depository Interests, or CDIs.

Peplin Pharmaceuticals for Life® is our registered trademark in the United States. Peplin®, Peplin Biotech®, PepTalk® and Peplin Pharmaceuticals for Life® 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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THE OFFERING

Common stock offered by us	Shares
Common stock to be outstanding after this offering	Shares
Use of proceeds	We expect to use the net proceeds from this offering to fund clinical development of our product candidates and for working capital and other general corporate purposes.
Proposed NASDAQ Global Market symbol	PLIN
Proposed ASX symbol for CDIs	PLI

The number of shares outstanding after this offering assumes the issuance by us of 9,229,069 shares of common stock in the Reorganization, which number of shares is based on 184,581,369 shares of Peplin Limited outstanding as of June 30, 2007. We have estimated the number of shares issuable by us in connection with the Reorganization by taking the number of ordinary shares of Peplin Limited outstanding and dividing that number by 20, which represents the exchange ratio in the Reorganization. However, the implementation agreement pertaining to the Reorganization provides that fractional shares issuable pursuant to the Reorganization will be rounded up to the nearest whole number. As a result, the actual number of shares we issue in the Reorganization will be slightly higher than that assumed for these purposes. The number of shares outstanding after this offering excludes:

- 741,272 shares of common stock issuable upon exercise of options to acquire our common stock that will be outstanding after the Reorganization and this offering, with a weighted average exercise price of $13.78 per share;
- 1,111,112 shares of our common stock that will be issuable in the Reorganization to certain investors that entered into subscription agreements with Peplin Limited on August 9, 2007 to acquire an aggregate of 22,222,222 shares of Peplin Limited; and
- an aggregate of 758,728 additional shares of our common stock reserved and available for issuance under our 2007 Incentive Award Plan.

Unless we indicate otherwise, all information in this prospectus:

- assumes the issuance by us of 9,229,069 shares of common stock in the Reorganization, based on the number of ordinary shares of Peplin Limited outstanding as of June 30, 2007 and assuming our issuance of 1 share for every 20 Peplin Limited ordinary shares;
- assumes our issuance of options to acquire 1,608,593 shares of our common stock, which options we expect to issue in replacement of outstanding options of Peplin Limited in connection with the Reorganization;
- assumes no exercise of the underwriters over allotment option; and

assumes all dollar amounts are in U.S. dollars and have been converted from Australian dollars using the foreign currency exchange rates as set forth on page 6 below.

As a result, unless the context otherwise states, references throughout this prospectus to we, us, our, Peplin or the company refer to the business of Peplin Limited and its subsidiaries for all periods prior to the consummation of the Reorganization, and to the business of Peplin, Inc. and its subsidiaries (including Peplin Limited) for all periods subsequent to the consummation of the Reorganization.

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SPECIAL NOTE REGARDING FOREIGN CURRENCY EXCHANGE RATES

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:

		Exchange Rate per Australian Dollar	
Year Ended June 30,		**For Revenues, Expenses and Compensation Numbers(1)**	**For Assets and Liabilities(2)**
	2007	$ 0.7925	$ 0.8491
	2006	$ 0.7472	$ 0.7423
	2005	$ 0.7568	$ 0.7618
	2004	$ 0.7155	$ 0.6952
	2003	$ 0.5884	$ 0.6713
Nine Months Ended March 31,			
	2007	$ 0.7779	$ 0.8104
	2006	$ 0.7459	$ 0.7165

(1) These exchange rates represent average exchange rates during the period.

(2) These represent the exchange rates as of June 30 or March 31, as applicable.

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SUMMARY FINANCIAL DATA

Prior to the Reorganization, Peplin, Inc. has no business or operations. As of the date of this prospectus, the business and operations of Peplin, Inc. consist solely of the business and operations of Peplin Limited.

Peplin Limited

The summary financial information set out below has been derived from the consolidated financial statements of Peplin Limited. We derived the summary audited consolidated statements of operations data presented below for each of the three years ended June 30, 2004, 2005 and 2006 and the unaudited consolidated statements of operations data for the period from inception to March 31, 2007 from the consolidated financial statements of Peplin Limited included elsewhere in this prospectus. We derived the summary consolidated statements of operations data from the years ended June 30, 2002 and 2003 from the unaudited consolidated financial statements of Peplin Limited that are not included in this prospectus. We derived the summary consolidated statements of operations data for the nine months ended March 31, 2006 and 2007 and the summary consolidated balance sheet data as of March 31, 2007 from the unaudited financial statements of Peplin Limited included elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with the audited financial statements. Interim financial results are not necessarily indicative of results that may be expected for the full fiscal year. You should read this financial data in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, the consolidated financial statements and accompanying notes of Peplin Limited, which are included elsewhere in this prospectus, Selected Financial Data and Balance Sheet of Peplin, Inc.

	Year Ended June 30,					Nine Months Ended March 31,		Period from Inception to March 31,
	2002	2003	2004	2005	2006	2006	2007	2007
	(Unaudited)	(Unaudited)				(Unaudited)	(Unaudited)	(Unaudited)
	(Amounts in thousands, except per share amounts)							
Consolidated Statements of Operations Data:								
Revenue	$	$ 39	$ 121	$ 5,610	$	$	$	$ 5,770
Cost of operations:								
Research and development	859	3,062	5,624	7,163	9,265	6,543	12,402	40,442
General and administrative	1,192	1,000	1,501	1,657	2,070	1,442	3,175	10,834
Loss from operations	(2,051)	(4,024)	(7,004)	(3,210)	(11,335)	(7,985)	(15,577)	(45,506)
Other income (expenses)	700	828	1,084	472	995	582	1,396	5,781

Net loss before income taxes	(1,351)	(3,196)	(5,920)	(2,738)	(10,340)	(7,403)	(14,182)	(39,725)
Income tax expense								
Net loss	$ (1,351)	$ (3,196)	$ (5,920)	$ (2,738)	$ (10,340)	$ (7,403)	$ (14,182)	$ (39,725)
Net loss per ordinary share(1):								
Basic and diluted	$ (0.03)	$ (0.05)	$ (0.08)	$ (0.03)	$ (0.09)	$ (0.06)	$ (0.08)	

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

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	As of March 31, 2007 (Unaudited) (In thousands)
Consolidated Balance Sheet Data:	
Cash and cash equivalents	$ 26,947
Working capital	22,180
Total assets	30,350
Non-current liabilities	72
Stockholders equity	24,637

Peplin, Inc.

The actual balance sheet data set forth below has been derived from our audited balance sheet as of the date of our incorporation, July 31, 2007.

	As of March 31, 2007		
	Actual	Pro Forma(1) (Unaudited)	Pro Forma as Adjusted(2) (Unaudited)
		(Amounts in thousands)	
Balance Sheet Data:			
Cash	$ 1	$ 26,947	$
Working capital		22,180	
Total assets	1	30,350	
Long-term liabilities		72	
Stockholders equity	$ 1	$ 24,637	

(1) On a pro forma basis to reflect the Reorganization and the issuance by us of 9,226,525 shares of our common stock to shareholders of Peplin Limited, based on 184,530,496 ordinary shares of Peplin Limited outstanding as of March 31, 2007.

(2) Pro forma as adjusted to also reflect the sale of shares of our common stock in this offering at an assumed public offering price of $ per share, after deducting estimated underwriting discounts and commissions and estimated expenses payable by us. Each $1.00 increase or decrease in the offering price per share would increase or decrease, respectively, each of cash and cash equivalents, working capital, total assets and stockholders equity by approximately $ million, after deducting estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1.0 million shares in the number of shares offered by us at the assumed offering price would increase or decrease each of cash and cash equivalents, working capital, total assets and stockholders equity by approximately $ million, after deducting estimated underwriting discounts and commissions payable by us.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risks, as well as all of the other information contained in this prospectus, before investing in our common stock. If any of the following events actually occur, our business, business prospects, cash flow, results of operations or financial condition could be harmed. In this case, the trading price of our common stock could decline, and you might lose all or part of your investment in our common stock. In assessing these risks, you should also refer to the other information contained in this prospectus, including the consolidated financial statements and related notes of Peplin Limited. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations.

Risks Related to Our Business and Industry

We have incurred 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 and other domestic and international capital raising activities. We are not profitable and have incurred 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, 2006 and the nine months ended March 31, 2007 were $10.3 million and $14.2 million, respectively. As of March 31, 2007, we had an accumulated deficit of $39.7 million. We expect to continue to incur 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 as well as the increased costs to operate as a company listed on the Australian Securities Exchange, or ASX, and on the NASDAQ Global Market. 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 Topical 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 Topical for AK. We are not permitted to market PEP005 Topical 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 an NDA until 2009, at the earliest.

Given the early stage of development of PEP005 Topical 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

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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.

We are actively engaged in a clinical trial related to PEP005 Topical for AK for facial applications, which is critical to advancing our regulatory approval process to the next phase of clinical development.

We believe the market for facial applications of our PEP005 Topical for AK is substantially larger than the market for non-facial applications. We are engaged in an ongoing open label Phase IIa clinical trial in Australia and New Zealand that is designed to evaluate the safety and efficacy of PEP005 Topical for AK as a field-directed therapy on the face and scalp. We believe this trial will help us determine the appropriate formulation strength for field-directed therapy on the face. As a result, the results of this trial are critical to the development of our Phase III clinical trial program, and we do not expect to approach the FDA regarding Phase III clinical trials until this trial is complete. We cannot assure you that the results from our ongoing Phase II clinical trial for AK will be sufficient to support our moving forward with Phase III clinical trials or that additional Phase II clinical trials will not be necessary. Moreover, while we recently reported preliminary results from our Phase II clinical trial of PEP005 Topical for AK in non-facial applications, those results are not necessarily indicative of the results we will obtain in our Phase II clinical trial for facial applications. Additionally, the FDA may impose greater scrutiny on the results from our Phase II clinical trial for facial application as there may be a greater safety concern for facial applications, and even if we believe the results from our Phase II clinical trial for facial applications are favorable, the FDA may disagree.

If we do not obtain favorable results in our clinical trials for facial applications of PEP005 for AK, we may alter our strategy with the FDA to initially seek approval for PEP005 for AK only for non-facial indications. If our only approved product is PEP005 Topical for AK for use in non-facial applications, our potential market and our ability to commercialize that product could be substantially reduced, which would negatively impact our business.

Even if we successfully complete our Phase II clinical program for PEP005 Topical for AK, if we are not able to successfully complete future Phase III clinical trials, we will not be able to commercialize that product candidate.

Phase II clinical trials are primarily designed to assess safety, not efficacy. The efficacy of PEP005 may not be demonstrated in larger Phase III clinical trials, even though the results of our Phase II clinical trials may appear compelling. We expect that we may have to conduct two Phase III clinical programs, one for the facial application and one for the non-facial application of PEP005 Topical for AK. 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. 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. Additionally, any Phase III clinical trials we commence may not achieve positive results, and, even if the results are positive, may not adequately support the results of any corresponding earlier trial. If we fail to complete our clinical trials for PEP005 Topical for AK, or if these clinical trials fail to demonstrate with substantial evidence that PEP005 Topical for AK is both safe and effective, we will not be able to commercialize the product in the United States or elsewhere and our business will be significantly harmed.

Our PEP005 Topical for the treatment of superficial BCC is at a much earlier stage than our AK treatment, and we cannot assure that this product 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 Topical for BCC. We are currently evaluating this product candidate when used as a lesion-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 at least two successful Phase III clinical trials for BCC before we can submit an NDA for this

indication.

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Results of clinical trials of PEP005 Topical for AK do not necessarily predict the results of clinical trials involving other indications. Clinical trials for PEP005 Topical 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 larger 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 Topical 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.

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. 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.

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 a vehicle in any indications for which the FDA requires a vehicle-controlled trial;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application 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 drug 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

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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 Topical 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.

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;

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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.

We do not currently conduct clinical trials on our own, and instead rely on third parties such as independent CROs and 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 several 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, despite the fact that these third-parties are not our employees, and we have limited ability to control the amount or timing of resources that they devote to our programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols or regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully

commercialize our product candidates. In addition, the execution of research and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another.

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

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

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

issue warning letters or untitled letters;

impose civil or criminal penalties;

suspend our regulatory approval;

suspend any of our ongoing clinical trials;

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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 products. 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 $2.8 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 Topical 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.

We will continue to need significant amounts of additional financing, which may not be available to us on favorable terms, or at all, and which may be dilutive to our stockholders. If we fail to obtain additional financing, we may be unable to fund our operations and commercialize our product candidates.

In order to commercialize our product candidates, we will need to conduct additional research and trials, obtain regulatory approval and develop manufacturing, sales and marketing capabilities. These activities will require substantial funds in addition to the funds received in connection with this offering.

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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.

Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience significant additional dilution in their ownership interest. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities. Moreover, additional funding may not be available to us on favorable terms, or at all. 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.

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.

If we are not able to secure additional funding in the manners described above when needed, we may be forced to delay, reduce the scope of or terminate our clinical trials.

PEP005 Topical for AK will have to compete effectively against well-established and accepted treatment alternatives.

The primary treatment for AK is currently cryotherapy, which is a quick and well-established treatment where the clinician removes the individual AK lesions by applying a cryogen, or extreme cold, for a sufficient period of time to destroy the lesion. 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 Topical for AK might be prescribed. We cannot assure you what type or amount of reimbursement will be available for our PEP005 Topical for AK. If physicians do not receive attractive reimbursement

for PEP005 Topical for AK, they may choose to prescribe other treatment alternatives, such as cryotherapy.

Moreover, there are other well-known and widely available topical agents for the treatment of AK. Our PEP005 Topical for AK will compete directly against these topical agents. To compete successfully, we must demonstrate compelling safety and efficacy data, particularly in comparison to that of other topical agents. To obtain appropriate comparative data, we may need to conduct a head-to-head clinical study with one or more of the competing topical agents to establish a superiority claim. Any studies of this type would be expensive and time consuming to run, and may fail to generate data sufficient to support PEP005 s superiority to these other topical agents.

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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 Topical for AK or PEP005 Topical for BCC, or any other product candidates that we may seek to commercialize, our revenues and prospects for profitability will suffer.

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

Our products may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Large private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payers, including Medicare, are challenging the prices charged for medical products and services, and many third-party payers limit or delay reimbursement for newly approved health care products. In particular, third-party payers may limit the covered

indications. Cost-control initiatives could cause us to decrease the price we might establish for our products, which could result in lower than anticipated product revenues. If the prices for our product candidates decrease or if governmental and other third-party payers do not provide adequate coverage or reimbursement, our prospects for revenue and for profitability will suffer.

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

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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.

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 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, nor do we expect a material portion of the proceeds of this offering to be used to advance these opportunities.

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. We may not be able to develop this capacity on a timely basis, or at all. If we are unable to establish sales and marketing capabilities, we will need to contract with third parties to market and sell our approved products in these locations. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States or other territories, our product revenue could be lower than if we directly marketed and sold our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

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

We have no patent protection for the compound PEP005 itself. Our basic patents are for the use of PEP005 and related compounds in the treatment of certain diseases. As a result, competitors who obtain the requisite regulatory approval may be able to offer products with the same active ingredient as PEP005 so long as they do not infringe any of our use and formulation patents. The first of our granted patents in the United States would expire in 2018, subject to any patent term extension which might be available under the Hatch-Waxman legislation. Similar laws in Europe and other jurisdictions may apply to extend foreign patent protection as well.

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;

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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 non-disclosure agreements that prohibit the disclosure of confidential information to any other parties. We require that our employees and consultants disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

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

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

In addition, we cannot guarantee that our patents, whether owned or licensed, or any future patents that may be issued, will prevent other companies from developing similar or functionally equivalent products. Further, we cannot guarantee that we will continue to develop our own patentable technologies or that our products or methods will not infringe upon the patents of third parties. 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. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States. In addition, we cannot guarantee that any of the patents that may be issued to us will effectively protect

our technology or provide a competitive advantage for our products or will not be challenged, invalidated, or circumvented in the future.

We are dependent on single source suppliers for components and materials used in our product candidates, and the loss of any of these suppliers could harm our business.

We rely on third-party suppliers for components and materials used in our product candidates and rely on single sources for some of the components necessary for the manufacture of our product candidates,

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including for the formulation and filling of our products. We generally acquire our single source components pursuant to purchase orders placed in the ordinary course of business, and we generally have no guaranteed supply arrangements with any of our single-source suppliers. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- increased component costs if these suppliers raise their prices;
- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms, or at all;
- our suppliers may make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products;
- if one of our supply relationships should be terminated, we may have difficulty locating and qualifying alternative suppliers, which we expect could take a year or longer; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

If we receive regulatory approval, it may become more difficult to quickly establish additional or replacement suppliers, particularly because of the FDA approval process. Any interruption or delay in the 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 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 plant for drying, milling, extraction and purification of PEP005. We outsource other manufacturing activities, such as formulation and filling, to third-party manufacturers. 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 Topical for AK, PEP005 Topical for BCC and any other product candidates depends 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 Topical for AK or PEP005 Topical 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

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