# United States SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended September 30, 2012

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-52998

# **Imprimis Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

45-0567010 (I.R.S. Employer Identification No.)

(State or other jurisdiction of incorporation or organization)

437 S. Hwy 101, Suite 209 Solana Beach, CA

(Address of principal executive offices)

92075

(Zip code)

<u>(858) 433-2800</u>

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\square$  No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company.

Large accelerated filer	0		Accelerated filer	0
Non-accelerated filer	0	(Do not check if a smaller reporting company)	Smaller reporting company	$\checkmark$

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

# APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS

Check whether the registrant filed all documents and reports required to be filed by Section 12, 13, or 15(d) of the Exchange Act of 1934 after the distribution of securities under a plan confirmed by a court. Yes o No o

As of November 13, 2012, 33,859,627 shares of the registrant's common stock, \$0.001 par value, were outstanding.

# IMPRIMIS PHARMACEUTICALS, INC. (A Development Stage Company)

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#### PART I FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

# IMPRIMIS PHARMACEUTICALS, INC. (A Development Stage Company) CONDENSED CONSOLIDATED BALANCE SHEETS

		September 30, 2012 (unaudited)	D	December 31, 2011
ASSETS				
Current assets				
Cash and cash equivalents	\$	10,990,871	\$	146,160
Prepaid expenses and other current assets		76,141		14,797
Deferred offering costs		383,746		-
Total current assets		11,450,758		160,957
Furniture and equipment, net		13,218		-
TOTAL ASSETS	\$	11,463,976	\$	160,957
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities				
Accounts payable and accrued expenses	\$	594,944	\$	218,612
Accounts payable - related party		-		56,087
Accrued Phase 3 expenses		55,784		55,784
Accrued payroll		19,115		-
Deferred revenue		-		100,000
Notes payable and accrued interest - related party		-		300,000
Convertible note payable and accrued interest	_	-		1,130,479
Total current liabilities		669,843		1,860,962
Commitments and contingencies				
STOCKHOLDERS' EQUITY (DEFICIT)				
Series A convertible preferred stock, \$0.001 par value, 10 shares authorized,				
none and 10 shares issued and outstanding				
at September 30, 2012 and December 31, 2011, respectively		-		-
Common stock, \$0.001 par value, 395,000,000 shares authorized,				
33,859,627 and 1,987,601 shares issued and outstanding				
at September 30, 2012 and December 31, 2011, respectively		33,860		1,988
Additional paid-in capital		33,411,513		16,818,740
Deficit accumulated during the development stage		(22,651,240)		(18,520,733)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)		10,794,133		(1,700,005)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$	11,463,976	\$	160,957

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

# IMPRIMIS PHARMACEUTICALS, INC. (A Development Stage Company) UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	For The Three MonthsFor The Three MonthsEndedEndedSeptember 30,September 30,20122011		hree Months Ended eptember 30,	For The Nine Months Ended September 30, 2012		Ended			For the Period From July 24, 1998 (Inception) through September 30, 2012	
Revenues:	¢		¢		¢	100.000	¢		¢	100.000
License revenues	\$	-	\$	-	\$	100,000	\$	-	\$	100,000
Operating Expenses:		0.4.6.001		(				511 500		11.010.001
Selling, general and administrative		946,381		66,496		2,240,004		514,529		11,813,331
Research and development		303,666		-	_	580,240		111,554	_	8,400,498
Loss from operations		(1,250,047)		(66,496)		(2,720,244)		(626,083)		(20,113,829)
Other income (expense):										
Interest expense		-		(18,904)		(24,658)		(56,095)		(1,730,892)
Interest income		4,221		-		9,805		-		137,386
Loss on extinguishment of debt		-		-		(1,195,410)		-		(1,195,410)
Gain on settlement		-		-		-		-		375,000
Gain on forgiveness of liabilities		-		-		-		-		176,505
Total other income (expense), net		4,221		(18,904)		(1,210,263)		(56,095)		(2,237,411)
Net loss		(1,245,826)		(85,400)		(3,930,507)		(682,178)		(22,351,240)
Deemed dividend to preferred stockholders		-		-		(200,000)		-		(300,000)
Net loss attributable to common stockholders	\$	(1,245,826)	\$	(85,400)	\$	(4,130,507)	\$	(682,178)	\$	(22,651,240)
Net loss attributable to common stockholders per common										
share, basic and diluted	\$	(0.04)	\$	(0.04)	\$	(0.22)	\$	(0.34)		
Weighted average common shares outstanding,										
basic and diluted		31,099,103		1,987,601		18,642,566		1,989,490		

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

# IMPRIMIS PHARMACEUTICALS, INC. (A Development Stage Company) UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

		For The Months Ended ptember 30, 2012	For The Nine Months Ended September 30, 2011			For the Period From July 24, 1998 (Inception) through september 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES Net loss	\$	(3,930,507)	\$	(682,178)	\$	(22,351,240)
Adjustments to reconcile net loss to net cash used in						
operating activities:						<b>A 177 0</b> 000
Estimated fair value of contributed services Gain on forgiveness of liabilities		-		-		2,475,000
Amortization of prepaid consulting fees		-		-		(176,505) 807,608
Depreciation		2,090		338		5,244
Loss on extinguishment of debt		1,195,410		-		1,195,410
Non-cash interest on notes payable		24,658		56,095		1,730,892
Stock-based compensation		1,502,080		149,162		3,630,896
Payments made on behalf of Company by related party		-		-		254,142
Changes in assets and liabilities:						
Prepaid consulting costs		-		-		(140,000)
Prepaid expenses and other current assets Accounts payable and accrued expenses		(61,344) 61,371		(13,876) 104,779		(76,141) 369,897
Accrued Phase 3 expenses		- 01,571		104,779		111,871
Accrued payroll		19,115		48,835		105,706
Deferred revenue		(100,000)		20,000		-
NET CASH USED IN OPERATING ACTIVITIES		(1,287,127)	-	(316,845)		(12,057,220)
CASH FLOWS FROM INVESTING ACTIVITIES						<u>, , , , , , , , , , , , , , , , , , , </u>
Purchases of fixed assets		(15,308)		-		(18,462)
NET CASH USED IN INVESTING ACTIVITIES		(15,308)		-		(18,462)
CASH FLOWS FROM FINANCING ACTIVITIES						
Proceeds from issuance of notes payable to a related party		450,000		-		976,300
Proceeds received in connection with debt modification		50,000		-		50,000
Proceeds from issuance of preferred stock		-		-		100,000
Proceeds from notes payable		-		-		2,500,000
Preferred stock deemed dividend paid at conversion Cash advances from related party		(200,000)		- 27,537		(200,000) 27,537
Repayment of advances from related party		-		21,331		(281,679)
Capital contributions		-		-		168,707
Net proceeds from purchase of common stock and						,
exercise of warrants and stock options		-		-		99,450
Proceeds from issuance of common stock and warrants						
for cash, net of offering costs		11,915,931		-		19,695,023
Deferred offering costs		(68,785)		-		(68,785)
NET CASH PROVIDED BY FINANCING ACTIVITIES		12,147,146		27,537		23,066,553
NET CHANGE IN CASH AND CASH EQUIVALENTS		10,844,711		(289,308)		10,990,871
CASH AND CASH EQUIVALENTS, beginning of period	¢	146,160	¢	291,462	¢	-
CASH AND CASH EQUIVALENTS, end of period	\$	10,990,871	\$	2,154	\$	10,990,871
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:						
Issuance of and adjustment to common stock and warrants to consulting firms for prepaid consulting fees	\$	-	¢	-	¢	422 007
Deferred offering costs in connection with equity	Э	-	\$	-	\$	432,007
offering recorded in accounts payable	\$	314,961	\$	-	\$	314,961
Conversion of related party accounts payable into common stock	\$	56,087	\$	-	\$	56,087
Conversion of notes payable and accrued interest into	+	, ,				,
common stock	\$	1,905,137	\$	-	\$	3,435,314
Forgiveness of notes payable and accrued interest to						
shareholders	\$	-	\$	-	\$	241,701
Conversion of advances to notes payable to shareholders	\$	-	\$	-	\$	196,300
Accretion of preferred stock discount	\$	-	\$ ¢	-	\$ ¢	100,000
Related party acquisition of Phase 3 liabilities Conversion of preferred stock into common stock	\$ \$	- 7,499	\$ \$	-	\$ \$	56,087 7,499
Conversion of preferred stock into common stock	Φ	/,477	Φ	-	Φ	/,477

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

#### IMPRIMIS PHARMACEUTICALS, INC. (A Development Stage Company) NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For the three and nine months ended September 30, 2012 and 2011 and the period from July 24, 1998 (Inception) through September 30, 2012

#### For the three and mile months ended September 30, 2012 and 2011 and the period from July 24, 1990 (Interprint) in the

# NOTE 1. OVERVIEW AND BASIS OF PRESENTATION

#### **Company and Background**

Imprimis Pharmaceuticals, Inc. ("Imprimis", the "Company", "we", "us", or "our") is a specialty pharmaceutical company developing non-invasive, topically delivered products. Our innovative patented Accudel cream formulation technology is designed to enable highly targeted site specific treatment. Impracor, our lead pain product candidate, utilizes the Accudel platform technology to deliver the active drug, ketoprofen, a non-steroidal anti-inflammatory drug, through the skin directly into the underlying tissues where the drug exerts its localized anti-inflammatory and analgesic effects.

Through our strategic relationship with Professional Compounding Centers of America, Inc. ("PCCA") (see Note 4 and Note 6), one of the largest drug compounding organizations in the world, we expect to facilitate our future selection, formulation and development of potential product candidates. Our relationship with PCCA is exclusive and provides us with the opportunity to develop new products using PCCA's proprietary drug formulations and drug delivery technologies, as well as access to an extensive database of market-oriented information related to a specific drug development opportunity. We plan to use our proprietary Accudel drug delivery technology, coupled with these licensed technologies, formulations and market data, to identify pharmaceutical development opportunities we perceive a significant unmet need for a new drug product. We are currently considering potential product candidates in the muscle relaxant and neuropathic pain fields, and we expect those areas may be our next avenues for additional product development.

#### **Basis of Presentation**

On February 28, 2012, the Company changed its name from Transdel Pharmaceuticals, Inc. to Imprimis Pharmaceuticals, Inc. All prior references to Transdel Pharmaceuticals, Inc. have been changed to Imprimis Pharmaceuticals, Inc. to reflect the change. On February 28, 2012, the Company effected a one-foreight reverse stock split. All share and per share amounts and calculations in this report reflect the effects of that reverse stock split.

Imprimis has prepared the accompanying interim condensed unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. For further information, refer to the Company's audited consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2011.

#### **Principles of Consolidation**

On September 17, 2007, Imprimis entered into an Agreement of Merger and Plan of Reorganization (the "Merger Agreement") by and among Imprimis, Transdel Pharmaceuticals Holdings, Inc., a privately held Nevada corporation ("Transdel Holdings"), and Trans-Pharma Acquisition Corp., a newly formed, wholly-owned Delaware subsidiary of Imprimis ("Acquisition Sub"). Upon closing of the merger transaction contemplated under the Merger Agreement (the "Merger"), Acquisition Sub merged with and into Transdel Holdings, and Transdel Holdings, as the surviving corporation, became a wholly-owned subsidiary of Imprimis. As a result of the Merger, the former owners of Transdel Holdings became the controlling stockholders of Imprimis. Accordingly, the merger of Transdel Holdings and Imprimis is a reverse merger that has been accounted for as a recapitalization of Transdel Holdings.

Effective on September 17, 2007, and for all reporting periods thereafter, Imprimis' operating activities, including any prior comparative period, include only those of Transdel Holdings. All references to share and per share amounts in the accompanying consolidated financial statements and footnotes have been restated to reflect the aforementioned share exchange. All significant intercompany accounts and transactions have been eliminated in consolidation.

On June 20, 2011, Transdel Holdings was merged with Imprimis Pharmaceuticals, Inc., at which time Transdel Holdings ceased as a corporation, and Imprimis Pharmaceuticals, Inc. remains as the sole surviving corporation.

#### **Development Stage Enterprise**

The Company is a development stage company as defined under Financial Accounting Standards Board ("FASB") guidance. The Company is devoting substantially all of its present efforts to establish a new business, and its planned principal operations have not yet commenced. All losses accumulated since inception have been considered as part of the Company's development stage activities.

These condensed consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The Company is a development state enterprise and has incurred recurring operating losses, has had negative operating cash flows and has not recognized any significant revenues since July 24, 1998 (inception). In addition, the Company has a deficit accumulated during the development stage of approximately \$22.7 million at September 30, 2012, and anticipates incurring further losses through the year 2012 and beyond. The Company has not yet generated commercial sales revenue and has funded its operating losses to date through debt and equity offerings and borrowings under its line of credit. The Company believes that its existing cash and cash equivalents will be sufficient to cover its cash flow requirements through the next twelve months.

#### **Research and Development**

The Company expenses all costs related to research and development as they are incurred.

#### **Revenue Recognition and Deferred Revenue**

The Company will recognize revenues in accordance with FASB guidance, which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred; (3) the selling price is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) will be based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectibility of those amounts. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments will be provided for in the same period the related sales are recorded. The Company will defer any revenue for which the product has not been rendered or are subject to refund until such time that the Company and the customer jointly determine that the product has been delivered or services have been rendered or no refund will be required.

For the nine months ended September 30, 2012, the Company recorded \$100,000 in revenues for non-refundable royalty advances, which were previously deferred. The Company does not anticipate that it will generate any significant revenues until one or more of its drug candidates are approved by the U.S. Food and Drug Administration ("FDA") and the Company is able to commercialize one or more of its product candidates. Also, effective sales and marketing support must be in place for either the drug candidates or any other products the Company may develop in order to generate any revenues. The FDA approval process is highly uncertain and the Company cannot estimate when it will generate revenues at this time from sales of its products.

#### **Income Taxes**

Income tax expense is provided for the tax effects of transactions reported in the financial statements and consists of taxes currently due, plus deferred taxes. Deferred taxes are recognized for differences between the basis of assets and liabilities for financial statement and income tax purposes. The differences relate primarily to the effects of net operating loss carry forwards and differing basis, depreciation methods, and lives of depreciable assets. The deferred tax assets represent the future tax return consequences of those differences, which will be deductible when the assets are recovered.

No income tax benefit (expense) was recognized for the nine months ended September 30, 2012 as a result of tax losses in this period and because deferred tax benefits, derived from the Company's prior net operating losses, were previously fully reserved. At September 30, 2012, the Company had federal and California net operating loss carryforwards of approximately \$14.1 million and \$13.6 million, respectively. The use of our net operating losses may be restricted in future years due to the limitations pursuant to IRC Section 382 on changes in ownership.

The Company is subject to taxation in the United States and California. The Company's tax years for 2000 and forward are subject to examination by the United States and state tax authorities due to the carry forward of unutilized net operating losses.

#### **Cash and Cash Equivalents**

Cash equivalents include short-term, highly liquid investments with maturities of three months or less at the time of acquisition.

#### **Concentrations of Credit Risk**

The Company places its cash with financial institutions deemed by management to be of high credit quality. The Federal Deposit Insurance Corporation ("FDIC") provides basic deposit coverage with limits to \$250,000 per owner. In addition to the basic insurance deposit coverage, the FDIC is providing temporary unlimited coverage for noninterest-bearing transaction accounts from December 31, 2010 to December 31, 2012. At September 30, 2012, the Company had approximately \$10.1 million in cash deposits in excess of FDIC limits.

#### **Furniture and Equipment**

Furniture and equipment is stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of three to five years.

Furniture and equipment, net, as of September 30, 2012 and December 31, 2011 consisted of the following:

	•	ember 30, 2012	December 31 2011	I,
Furniture and Equipment, net:				
Computer Software and Hardware	\$	6,341	\$	-
Furniture and Equipment		8,967		-
		15,308		-
Accumulated Depreciation		(2,090)		-
	\$	13,218	\$	-

During the three and nine months ended September 30, 2012, the Company recorded depreciation expenses of \$843 and \$2,090, respectively, and during the three and nine months ended September 30, 2011, the Company recorded depreciation expenses of \$0 and \$338, respectively.

#### **Deferred Offering Costs**

On July 25, 2012, the Company filed with the Securities and Exchange Commission a registration statement in connection with a proposed offering of its common stock. At September 30, 2012, the Company had deferred offering costs of \$383,746 for legal, accounting and other expenses directly related to the proposed offering. Any cash proceeds the Company may receive from the proposed offering will be netted against these deferred offering costs and any future costs directly associated with the offering. There is no obligation to consummate an offering and an offering may not occur.

## **Deferred Rent**

The Company accounts for rent expense related to its operating leases by determining total minimum rent payments on the leases over their respective periods and recognizing the rent expense on a straight-line basis. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year is recorded as an adjustment to deferred rent. The deferred rent balance at September 30, 2012 was \$1,734 and is included in accounts payable and accrued expenses in the accompanying unaudited condensed consolidated balance sheet.

#### **Fair Value Measurements**

Fair value measurements are determined based on the assumptions that market participants would use in pricing an asset or liability. GAAP establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. The established fair value hierarchy prioritizes the use of inputs used in valuation methodologies into the following three levels:

- Level 1: Quoted prices (unadjusted) for identical assets or liabilities in active markets. A quoted price in an active market provides the most reliable evidence of fair value and must be used to measure fair value whenever available.
- Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Significant unobservable inputs that reflect a reporting entity's own assumptions about the assumptions that market participants would use in pricing an asset or liability. For example, level 3 inputs would relate to forecasts of future earnings and cash flows used in a discounted future cash flows method.

The fair values of the Company's cash and cash equivalents, accounts payable, and accrued expenses approximate carrying values due to their short term maturities.

# **Beneficial Conversion Features and Debt Discounts**

The convertible features of debt provide for a rate of conversion that is below market value. Such feature is normally characterized as a "beneficial conversion feature" ("BCF"). The relative fair values of the BCF were recorded as discounts from the face amount of the respective debt instrument. The Company amortized the discount using the effective interest method through maturity of such instruments.

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

All share-based payments to employees, including grants of stock options to employees, directors and consultants and restricted stock grants, are recognized in the financial statements based upon their fair values.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows FASB guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during their vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultants, the fair value of the equity instrument is primarily recognized over the term of the consulting agreement. In accordance with FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company records the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in its consolidated balance sheets.

The Company recorded stock-based compensation related to equity instruments granted to employees, directors and consultants as follows:

	For The Three Months Ended September 30, 2012		Ended Months Ended er 30, September 30,		For The Nine Months Ended September 30, 2012		Mo	or The Nine onths Ended ptember 30, 2011
Employees - selling, general and administrative	\$	180,630	\$	32,757	\$	298,854	\$	104,675
Employees - research and development		61,299		-		143,711		37,754
Directors - selling, general and administrative		331,264		4,041		898,679		6,733
Consultants - selling, general and administrative		80,849		-		160,836		-
Total	\$	654,042	\$	36,798	\$	1,502,080	\$	149,162

#### **Basic and Diluted Loss per Common Share**

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants outstanding during the period.

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock or, "if converted" method) from convertible notes, preferred stock, stock options, unvested restricted stock units ("RSUs") and warrants were 8,345,388 and 395,846 at September 30, 2012 and 2011, respectively, and are excluded from the calculation of diluted net loss per share for all periods presented because the effect is anti-dilutive.

The following table shows the computation of basic and diluted earnings per common share for the three- and nine-month periods ended September 30, 2012 and September 30, 2011:

	For the three months ended September 30, 2012		For the three months ended September 30, 2011		For the nine months ended September 30, 2012		n	For the nine nonths ended eptember 30, 2011
Net loss	\$ (1,245,	,826)	\$	(85,400)	\$	(3,930,507)	\$	(682,178)
Deemed dividend to preferred stockholders		-		-		(200,000)		-
Numerator – loss attributable to common stockholders	\$ (1,245,	,826)	\$	(85,400)	\$	(4,130,507)	\$	(682,178)
Denominator – weighted average								
number of shares outstanding, basic and diluted	31,099,	103		1,987,601		18,642,566		1,989,490
Loss per share, basic and diluted	\$ (0	0.04)	\$	(0.04)	\$	(0.22)	\$	(0.34)

# Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting periods. Significant estimates made by management are, among others, the valuation of contributed services, deferred taxes and stock-based compensation issued to employees and non-employees. Actual results could differ from those estimates.

## NOTE 2. BANKRUPTCY PETITION AND ASSET PURCHASE AGREEMENT

On June 26, 2011, the Company filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the "Bankruptcy Court"), Case No. 11-10497-11 (the "Chapter 11 Case"). In connection with the Chapter 11 Case, the Company, as seller, and Cardium Healthcare, Inc., a wholly-owned subsidiary of Cardium Therapeutics, Inc., as purchaser ("Cardium"), entered into an Asset Purchase Agreement dated June 23, 2011 (the "Asset Purchase Agreement") pursuant to which the Company agreed to sell substantially all of its assets pursuant to Sections 105, 363 and 365 of the Bankruptcy Code, subject to court approval and the satisfaction of certain conditions set forth in the Asset Purchase Agreement.

Consummation of the sale to Cardium was subject to a number of conditions, including, among others, the approval by the Bankruptcy Court of the transactions contemplated by the Asset Purchase Agreement and compliance with certain specified deadlines for actions in connection with the Bankruptcy Case. The Asset Purchase Agreement was terminable by the parties under a number of circumstances, including failure to obtain certain Bankruptcy Court orders by agreed dates.

On July 26, 2011, the Bankruptcy Court denied the Company's motion to sell its assets pursuant to the Asset Purchase Agreement. On October 7, 2011, the Company terminated the Asset Purchase Agreement pursuant to its terms. On November 21, 2011, in connection with certain transactions with DermaStar International, LLC ("DermaStar") described in Notes 4 and 5 below, the Company requested that the Bankruptcy Court dismiss the Chapter 11 Case and retain jurisdiction to decide matters related to claims brought in the Bankruptcy Case by the Purchaser. On December 8, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case. In connection with the dismissal of the Chapter 11 Case, the Bankruptcy Court, among other things, declined to retain jurisdiction over claim objection proceedings and found moot the Company's objection to certain claims to receive a break-up fee pursuant to the Asset Purchase Agreement of Cardium Therapeutics, Inc. and Cardium Healthcare, Inc., a wholly owned subsidiary of Cardium. The dismissal of the Chapter 11 Case was based upon the provisions of both 11 U.S.C. Sections 305 (a) and 1112(b).

## NOTE 3. NOTES PAYABLE – RELATED PARTY

DermaStar is a former control person of the Company and had the ability to direct or cause direction of management and policies of the Company through its ownership of the Company's capital stock. Also, Dr. Robert Kammer, a director and the Chairman of the Board of the Company, and Mark L. Baum, Chief Executive Officer and a director of the Company, were managing members and partial owners of DermaStar. In July 2012, the Company was informed by DermaStar that it had dissolved and distributed all of its shares of the Company's capital stock held by it to its members. As a result of that dissolution and distribution, DermaStar is no longer a control person of the Company.

#### Convertible Note - April 2010

On April 5, 2010, the Company issued a Senior Convertible Promissory Note (the "Note") to Alexej Ladonnikov in a private placement. The Note included an annual interest rate of 7.5% and (unless converted or prepaid, as noted below) all principal and interest was due and payable on its maturity date of April 5, 2012 ("Maturity Date"). At any time prior to the Maturity Date, the investor had the right to convert all or a portion of the outstanding principal and accrued interest at a conversion ratio of one share of the Company's common stock for each \$8 (the fair market value of the Company's common stock on April 5, 2010) owed. Also, at any time prior to the Maturity Date, the Company had the option to prepay the outstanding principal and accrued interest. The Company received gross proceeds from the issuance of the Note in the aggregate amount of \$1,000,000. There were no discounts or commissions paid in connection with this private placement. Accrued interest on the Note was \$0 and \$130,479 at September 30, 2012 and December 31, 2011, respectively, and interest expense on the Note for the three and nine months ended September 30, 2012 was \$0 and \$12,123, respectively, and for the three and nine months ended September 30, 2011 was \$18,904 and \$56,095, respectively. Following the Company's bankruptcy petition filed June 26, 2011, as well as the change in ownership control following the issuance of Series A Convertible Preferred Stock to DermaStar, the entire unpaid principal sum of this Note, together with its accrued and unpaid interest became immediately due and payable.

In January 2012, DermaStar acquired 80% of the Note in a private transaction with Mr. Ladonnikov. On January 25, 2012, the Board of Directors of the Company approved, and the Company entered into, separate waiver and settlement agreements with DermaStar and Mr. Ladonnikov, the two parties holding the Note.

In connection with each of the waiver and settlement agreements, the holders of the Note each agreed to forever waive their rights to (i) accelerate the entire unpaid principal sum of the Note and all accrued interest pursuant to Section 1 of the Note related to the Company's bankruptcy petition filed June 26, 2011, (ii) Section 7 of the Senior Convertible Note Purchase Agreement dated April 5, 2010, regarding the designation and creation of the Series A Convertible Preferred Stock ("Series A Preferred Stock") and (iii) certain conversion rights pursuant to Section 3 of the Note related to the change of control that resulted from the sale of the Series A Preferred Stock.

Pursuant to the terms of the waiver and settlement agreement by and between the Company and DermaStar, DermaStar and the Company agreed to the mandatory conversion of the eighty percent (80%) of the principal and accrued and unpaid interest of the Note held by DermaStar, at such time as (and not until) the Company has a sufficient number of authorized common shares to effect such a conversion, into common stock of the Company at a conversion price of approximately \$0.13336 ("DermaStar Conversion Price"). Additionally, DermaStar agreed to a mandatory conversion of an additional \$56,087 current accounts payable of the Company ("AP Conversion") held by DermaStar, at such time as (and not until) the Company had a sufficient number of authorized common shares for such conversion. The AP Conversion was made at the DermaStar Conversion Price.

On February 28, 2012, the Company issued 7,274,812 common shares to DermaStar as payment in full for its 80% ownership of the Note (\$800,000), its related accrued interest (\$114,082) and \$56,087 in the Company's accounts payable. The Company has determined this to be a substantial modification to the debt instruments and has applied debt extinguishment accounting to record a loss on extinguishment of debt of \$856,087 for the nine months ended September 30, 2012.

Pursuant to the terms of the waiver and settlement agreement by and between the Company and Mr. Ladonnikov, Mr. Ladonnikov and the Company agreed to the mandatory conversion of the twenty percent (20%) of the principal and accrued and unpaid interest of the Note held by Mr. Ladonnikov, at such time as (and not until) the Company had a sufficient number of authorized common shares to effect such a conversion, into common stock of the Company at a conversion price of \$0.12. Additionally, Mr. Ladonnikov agreed to make a one-time payment to the Company, at such time as the Note is converted into Company common stock, of \$50,000.

On February 28, 2012, the Company received payment from Mr. Ladonnikov of \$50,000 and issued 1,904,338 common shares to Mr. Ladonnikov as payment in full for his 20% ownership of the Note (\$200,000) and its related accrued interest (\$28,521). The Company has determined this to be a substantial modification to the debt instrument and has applied debt extinguishment accounting to record a loss on extinguishment of debt of \$150,000 (\$200,000 Note principal balance less \$50,000 cash payment received) for the nine months ended September 30, 2012.

# Secured Line of Credit

On November 21, 2011, the Company entered into a Secured Line of Credit Letter Agreement (the "Line of Credit Agreement") with DermaStar. The Line of Credit Agreement became effective on December 10, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. The line of credit was secured by a blanket security interest in all of the Company's assets, including its intellectual property. The Line of Credit Agreement provided for advances to the Company of up to an aggregate of \$750,000 (each an "Advance" and collectively the "Loan"), subject to the satisfaction by the Company of certain conditions in connection with the initial Advance and each subsequent Advance. Each Advance was made pursuant to a promissory note in favor of DermaStar. The Company had received advances totaling \$750,000 and \$300,000 up to April 25, 2012 (the date of the conversion thereof) and December 31, 2011, respectively. The promissory notes accrued interest at 10% annually and had a maturity of one year after the effective dates of the applicable Advance. There was no accrued interest on the promissory notes at September 30, 2012 and interest expense for the three and nine months ended September 30, 2012 was \$0 and \$12,534, respectively.

As of April 20, 2012, the aggregate principal balance owing under the Line of Credit was \$750,000. Effective April 20, 2012, the Company and DermaStar entered into a Promissory Note Conversion Agreement (the "Conversion Agreement") wherein the parties agreed that the entire outstanding principal balance of the promissory notes issued in favor of DermaStar pursuant to the Line of Credit Agreement and all related accrued interest, totaling \$762,534, would be converted into shares of the Company's common stock and warrants to purchase the Company's common stock on the same terms as the issuance of such securities in the April Private Placement (as described in Note 4). Pursuant to the Conversion Agreement, on April 25, 2012 and upon conversion of the outstanding principal balance and unpaid interest under the Line of Credit Agreement, DermaStar was issued a total of 965,233 shares of the Company's common stock and a related warrant to purchase up to an additional 241,308 shares of the Company's common stock. The warrant has an exercise price of \$1.185 per share and a three year term. The Line of Credit Agreement has been terminated.

The addition of a conversion feature to the Line of Credit Agreement resulted in terms that were substantially different from the terms of the original agreement, and therefore, the conversion resulted in an extinguishment of debt. The relative fair value of the warrant issued to DermaStar was determined to be \$137,383 using the Black-Scholes-Merton valuation model. The variables used in this pricing model included: (1) discount rate of 0.4% (2) expected warrant life of 3 years, (3) expected volatility of 350% and (4) zero expected dividends. In addition, the value of the effective BCF resulting from the Conversion Agreement was determined to be \$51,940. The value of the debt discount was recorded as additional paid-in capital and as the Line of Credit is immediately convertible, the debt discount of \$189,323 was immediately expensed as a loss on extinguishment of debt.

Notes payable consist of the following:

	September 30,		December 31,
	2012		2011
10% convertible notes	\$	-	\$ 300,000
7.5% convertible note		-	1,000,000
Total convertible notes payable	\$	-	\$ 1,300,000
Less: Current portion		-	(1,300,000)
Long-term portion	\$	_	\$

# NOTE 4. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

#### **Common Stock**

On February 28, 2012, the Company increased the number of authorized shares of capital stock to 400,000,000, and the number of authorized shares of common stock to 395,000,000 and effected a one-for-eight reverse stock split. All share and per share amounts and calculations in this report reflect the one-for-eight reverse stock split.

On February 28, 2012, the Company issued 1,904,338 common shares to Alexej Ladonnikov as payment in full for his 20% ownership of the Note (\$200,000) and its related accrued interest (\$28,521).

On February 28, 2012, the Company issued 7,274,812 common shares to DermaStar as payment in full for its 80% ownership of the Note (\$800,000), its related accrued interest (\$114,082) and \$56,087 in the Company's accounts payable.

On April 20, 2012, the Company entered into a Securities Purchase Agreement with certain accredited investors relating to the sale and issuance of an aggregate of 10,058,455 shares of its common stock and warrants to purchase up to 2,514,642 shares of its common stock at an exercise price of \$1.185 per share, for an aggregate purchase price of approximately \$7,950,000 (the "April Private Placement"). The April Private Placement closed on April 25, 2012, and the Company received proceeds, net of offering costs, of approximately \$7,930,000.

On April 25, 2012, the Company converted debt totaling \$762,534 (including accrued interest of \$12,534) owed to DermaStar, a related party, into 965,233 shares of the Company's common stock and a related warrant to purchase 241,308 shares of the Company's common stock at an exercise price of \$1.185 per share on the same terms as the issuance of such securities in the April Private Placement (see Note 3).

On August 30, 2012, the Company entered into a License Agreement (the "PCCA License Agreement") and a Stock Purchase Agreement (the "PCCA Purchase Agreement") in a strategic transaction with PCCA (the "PCCA Transaction"). Pursuant to the terms of the PCCA Purchase Agreement, on August 31, 2012, the Company issued and sold to PCCA 4,163,414 shares of its common stock at a per share purchase price of \$0.96075, for aggregate proceeds, net of offering costs, of approximately \$3,980,000.

#### **Preferred Stock**

At September 30, 2012, the Company had 5,000,000 shares of preferred stock, \$0.001 par value, authorized and no shares of preferred stock issued and outstanding.



#### Series A Preferred Stock - Converted

On December 12, 2011, the Company issued 10 shares of Series A Preferred Stock to DermaStar, a related party, in a private placement. The Series A Preferred Stock has the rights and preferences identified in the Certificate of Designation to our Amended and Restated Certificate of Incorporation filed with the Delaware Secretary of State on December 9, 2011. Among other things, the Certificate of Designation (i) authorizes 10 shares of the Company's preferred stock to be designated as "Series A Convertible Preferred Stock"; (ii) grants the holders of the Series A Preferred Stock the right to convert into our common stock at a conversion price of approximately \$0.013336, as adjusted; (iii) grants a liquidation preference of \$10,000 per share of Series A Preferred Stock; (iv) provides that the holders of Series A Preferred Stock shall vote with the holders of our common stock on an "as converted basis"; and (v) provides that the affirmative vote of a majority of the outstanding shares of the Series A Preferred Stock is required to approve certain corporate matters including, among other things, changes to the rights of the holders of the Series A Preferred Stock, amendments to our Amended and Restated Certificate of Incorporation or Bylaws, issuance of priority or parity securities, issuance of debt securities, entry into certain fundamental transactions and increase or decrease in the size of our Board of Directors.

On June 29, 2012, DermaStar converted the 10 shares of Series A Preferred Stock held by it into 7,498,500 shares of the Company's common stock. In connection with the conversion, the Company paid to DermaStar \$200,000 as partial consideration for the conversion pursuant to a conversion agreement. Immediately following the conversion of the Series A Preferred Stock, all 10 shares were retired to our treasury and cancelled. The Company recognized the \$200,000 payment as additional consideration transferred in the transaction in excess of the fair value of the consideration issuable in accordance with the original conversion terms. As a result, the cash payment to DermaStar was recorded as a deemed preferred stock dividend. Accordingly, the Company recorded a deemed preferred stock dividend at the date of conversion, June 29, 2012, totaling \$200,000, which represents an increase to reported net loss in arriving at net loss attributable to common stockholders.

# **Restricted Stock Units ("RSUs")**

RSU awards are granted subject to certain restrictions, including performance based conditions. The grant-date fair value of the RSUs, which has been determined based upon the market value of the Company's shares on the grant date, is expensed over the vesting period.

On July 18, 2012, the Company granted to Mr. Baum, in connection with his services as the Chief Executive Officer, 800,000 RSUs pursuant to a Stand-alone Restricted Stock Unit Agreement (the "Baum RSUs") outside of the Company's 2007 Incentive Stock and Awards Plan, as amended on November 5, 2008, January 25, 2012 and July 18, 2012 (the "Plan"). The Baum RSUs are subject to certain performance-based vesting criteria, such that 200,000 RSUs will vest upon the satisfaction of each of the following events: (i) successful completion of a financing that results in aggregate cash proceeds to the Company of at least \$5,000,000 at any time following the effective date of the grant; (ii) the Company meets the primary endpoints of its Phase 3 clinical studies for its drug candidate, Impracor; (iii) the Company submits a New Drug Application for Impracor to the U.S. Food and Drug Administration; and (iv) the Company enters into a definitive license, collaboration or similar agreement for Impracor that would reasonably be expected to generate cash flow for the Company. The Baum RSUs vest in full upon a change in control of the Company. The Company has accounted for the Baum RSUs based on an assumption of the full satisfaction of its performance-based vesting criteria.

On July 18, 2012, the Company granted to Dr. Kammer, in connection with his services as a consultant and advisor to the Company, 200,000 RSUs, pursuant to a Stand-alone Restricted Stock Unit Agreement (the "Kammer RSUs") outside of the Plan. The Kammer RSUs are subject to certain performance-based vesting criteria, such that all 200,000 RSUs will vest when the Company meets the primary endpoints of its Phase 3 clinical studies for its drug candidate, Impracor. The Kammer RSUs vest in full upon a change in control of the Company. The Company has accounted for the Kammer RSUs based on an assumption of the full satisfaction of its performance-based vesting criteria. In accordance with accounting guidance for share-based compensation to consultants, the unvested portion of the Kammer RSUs will be revalued on an interim basis until the performance-based vesting criteria is met. Once the performance-based vesting criteria is met, the fair value and total expense amount of the Kammer RSUs will be calculated based on the market value of the Company's common stock on that day. On the date of issuance, July 18, 2012, the Kammer RSUs were valued at \$130,000, and as of September 30, 2012, the revalued estimated fair value of the Kammer RSUs was \$380,000.

A summary of the Company's RSU activity and related information for the nine months ended September 30, 2012 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested – January 1, 2012	-	\$ -
RSUs granted	1,000,000	0.65
RSUs vested	-	-
RSUs cancelled	-	-
Unvested - September 30, 2012	1,000,000	\$ 0.65

The grant-date fair value of RSUs granted during the nine month period ended September 30, 2012 was approximately \$650,000. As of September 30, 2012, the total unrecognized compensation expense related to unvested RSUs was approximately \$685,000 (including recognized and unrecognized expenses of the revalued fair value of the Kammer RSUs) which is expected to be recognized over a weighted-average period of 1 year, based on estimated vesting schedules.

# **Stock Option Plan**

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Plan, which, as of September 30, 2012, provided for the issuance of a maximum of an aggregate of 12,000,000 shares of the Company's common stock. The purpose of the Plan is to provide an incentive to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plan, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-qualified stock options and restricted stock. The Plan will be administered by the Company's Board of Directors until such time as such authority has been delegated to a committee of the Board of Directors. On January 25, 2012, our stockholders approved an amendment to the Plan to increase the number of shares available for issuance under the Plan from 375,000 to 3,750,000 and to modify the definition of "fair market value" under the Plan, among other things. The approval became effective on February 26, 2012. Effective as of July 18, 2012, our board of directors and stockholders holding a majority of the Company's outstanding voting power approved a further amendment to the Plan to increase the number of shares of the company's outstanding voting power approved a further amendment to the Plan to increase the number of shares of the company's outstanding voting power approved a further amendment to the Plan to increase the number of shares of the Company's outstanding voting power approved a further amendment to the Plan to increase the number of shares of the Company's common stock that may be granted to an individual under the Plan in a calendar year.

A summary of the Plan activity for the nine months ended September 30, 2012 is as follows:

			ed Avg.	Weighted Avg. Remaining		Aggregate
	Number of shares	Exerci	se Price	Contractual Life	In	trinsic Value
Options outstanding - December 31, 2011	150,152	\$	9.68			
Options granted	5,060,616		0.73			
Options exercised	-					
Options cancelled	(718,750)		0.67			
Options outstanding - September 30, 2012	4,492,018	\$	1.04	5.01	\$	5,072,416
Options exercisable - September 30, 2012	1,847,652	\$	1.45	5.59	\$	2,038,108
Options vested and expected to vest - September 30, 2012	4,227,582	\$	1.06	5.04	\$	4,768,985

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on September 28, 2012, based on the closing price of the Company's common stock of \$1.90 on that date.

On January 25, 2012, the Board approved the grant to Dr. Balbir Brar, the Company's President, of an option to purchase 1,125,000 shares of common stock under the Plan. The exercise price of the option is \$0.736 and the option vests as follows: 1/36<sup>th</sup> of the unvested shares will vest on each of the 36 monthly periods following the date of the grant provided Dr. Brar continues to be employed by the Company as of the applicable vesting date.

On January 25, 2012, in connection with a senior advisory agreement, the Board approved the grant to Dr. Paul Finnegan, a director, an option to purchase up to 625,000 shares of common stock under the Plan. The exercise price of the option is \$0.64. The option was originally scheduled to vest as follows: 250,000 shares on January 6, 2013, 250,000 shares on January 6, 2014 and 125,000 on January 6, 2015. On May 9, 2012, the Company entered into a termination agreement to terminate its senior advisory agreement with Dr. Finnegan, and, in connection therewith, entered into an amendment to Dr. Finnegan's option agreement. The amendment to the option agreement modifies the vesting schedule of the option to provide that 40% of the shares covered by the grant will vest on September 30, 2012, 40% will vest on March 31, 2013 and 20% will vest on September 30, 2013, provided that Dr. Finnegan is serving as a director, employee or consultant at the time of such vesting. In connection with the termination of the senior advisory agreement, the option as compensation for Dr. Finnegan's services as a director rather than a consultant. This option is accounted for as an employee stock option agreement, the final valuation of the option was determined at the date of modification and the remaining expense of the option agreement will be recognized ratably over the remaining vesting periods in accordance with the modified terms.

On January 25, 2012, the Board approved a one-time stock option grant to Mr. Baum, the Company's current Chief Executive Officer and a director, to purchase up to 625,000 shares of the Company's common stock under the Plan. The option was issued to Mr. Baum for his uncompensated services as Chairman of the Board and significant ongoing services related, but not limited to, the Company's emergence from Chapter 11 bankruptcy protection, negotiation with creditors, pursuit of additional financing opportunities and hiring of executive officers. The option vests in twelve equal monthly periods, commencing on January 25, 2012 and ending on January 25, 2013 and has an exercise price of \$0.48.

On January 25, 2012 the Board approved the grant to Andrew R. Boll, the Company's Vice-President of Accounting and Public Reporting, of an option to purchase up to 75,000 shares of common stock under the Plan, which option was granted on February 1, 2012, the commencement date of Mr. Boll's employment with the Company. The exercise price of the option is \$0.736 and the option vests as follows: 1/36<sup>th</sup> of the unvested shares will vest on each of the 36 monthly periods following the date of the grant provided Mr. Boll continues to be employed by the Company as of the applicable vesting date.

On January 25, 2012 the Board approved the grant to Dr. Joachim Schupp, the Company's Chief Medical Officer, of an option to purchase up to 375,000 shares of common stock under the Plan, which option was granted on February 15, 2012, the commencement date of Dr. Schupp's employment with the Company. The exercise price of the option is \$0.72 and the option vests as follows: 1/36<sup>th</sup> of the unvested shares will vest on each of the 36 monthly periods following the date of the grant provided Dr. Schupp continues to be employed by the Company as of the applicable vesting date.

On April 1, 2012, the Board of Directors approved the issuance of options to purchase 125,000 shares of the Company's common stock to each of the Company's directors, including the Company's employee and non-employee directors, under the Plan. Each of the options has an exercise price of \$0.90 per share. The options have a term of five years and vest quarterly over a one year period, such that the option to purchase 31,250 shares vests on each of June 30, 2012, September 30, 2012, December 31, 2012 and March 31, 2013.

On April 1, 2012, in recognition and consideration for his services as a director to the Company during 2010 and 2011, the Board approved the issuance to Dr. Jeff Abrams of an additional option to purchase 300,000 shares of the Company's common stock with an exercise price of \$0.90 per share under the Plan. The option has a ten year term and vests monthly over a one year period.

On April 1, 2012, the Company granted to Mr. Baum an option to purchase up to 300,000 shares of the Company's common stock at an exercise price of \$0.90 per share under the Plan. The option terminates on March 31, 2017 and vests over a two year period, with 75,000 options vesting immediately upon issuance and an additional 9,375 options vesting monthly for the next twenty four months thereafter.

Effective as of the close of business on July 25, 2012, Dr. Brar submitted his resignation as a director on the Board of Directors of the Company. Dr. Brar continues in his capacity as the President of the Company. At the time of his resignation as a director, options to purchase 31,250 shares had vested under Dr. Brar's April 1, 2012 option grant related to his Board service, and all unvested shares subject to the option were forfeited. Dr. Brar was granted an extension of 240 days from his resignation date to exercise the 31,250 vested shares.

On July 26, 2012, the Board of Directors of the Company appointed Stephen G. Austin, CPA, as a new director on the Board of Directors of the Company. In connection with his appointment as a director, the Board approved the issuance to Mr. Austin of an option to purchase up to 85,616 shares of the Company's common stock under the Plan. Such option has an exercise price of \$0.90 per share, has a term of five years, and vests monthly over a period of one year commencing on January 1, 2013.

The table below illustrates the fair value per share determined by the Black-Scholes-Merton option pricing model with the following assumptions used for the grants issued to employees and directors during the nine months ended September 30, 2012:

	Nine Months Ended September 30, 2012
Weighted-average fair value of options granted	\$ 0.65
Expected terms (in years)	2.5-5.5
Expected volatility	219-360%
Risk-free interest rate	0.31-1.03%
Dividend yield	-

Effective April 1, 2012, the Company entered into an advisory agreement with director Dr. Robert Kammer (the "Advisory Agreement") pursuant to which Dr. Kammer will provide certain services to the Company in addition to his services as a director, including, but not limited to, providing management and advice regarding the operations of the registration clinical trials including start-up and on-going clinical operational and development activities, manufacturing and quality control of the clinical and commercial supplies, project and operational management, assistance in the identification of new drug delivery technologies that may be available for acquisition or license and assistance in the development of the Company's intellectual property. As part of Dr. Kammer's compensation under the Advisory Agreement, the Company granted to Dr. Kammer on April 1, 2012 an option to purchase up to 300,000 shares of the Company's common stock at an exercise price of \$0.90 per share under the Plan. The option terminates on March 31, 2017 and vests over a two year period, with 75,000 options vesting immediately upon issuance and an additional 9,375 options vesting monthly for the next twenty four months thereafter. In accordance with accounting guidance for share-based compensation to consultants, the unvested portion of the option will be revalued on an interim basis until the termination of the Advisory Agreement. The Advisory Agreement is to terminate on the earlier of the completion of the services or the second anniversary of the date of the agreement. As of September 30, 2012, the revalued aggregate estimated fair value of the stock option, based on the Black-Scholes-Merton pricing model, was \$338,420.

The table below illustrates the fair value per share determined by the Black-Scholes-Merton option pricing model with the following assumptions used for the grants issued to consultants during the nine months ended September 30, 2012:

	Nine Months Ended September 30, 2012
Weighted-average fair value of options granted	\$ 1.46
Expected terms (in years)	4.50-5.00
Expected volatility	306% - 361%
Risk-free interest rate	0.62%-1.03%
Dividend yield	-

The Company's outstanding options have been granted to the employees, directors and consultants at exercise prices that range from \$0.48 to \$16.00, the estimated fair market value of the common stock on the dates of issuance. These options have expiration dates that range from 4 - 10 years from their grant date and vest immediately, monthly, quarterly, or on an annual basis for a period of up to five years. The Company uses the Black-Scholes-Merton option pricing model to estimate the grant-date fair value of share-based awards. The Black-Scholes-Merton model requires subjective assumptions regarding future stock price volatility and expected time to exercise, along with assumptions about the risk-free interest rate and expected dividends, which affect the estimated fair values of the Company's stock-based awards. The expected term of options granted was determined in accordance with the "simplified approach" as the Company has limited historical data on employee exercises and post-vesting employment termination behavior. The expected volatility is based on the historical volatilities of the common stock of the Company. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the expected term of the grant effective as of the date of the grant. The Company used 0% as an expected dividend yield assumption. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant.

The Company issued options to purchase up to 5,060,616 shares of the Company's common stock during the nine months ended September 30, 2012. The weighted average fair value per share of grants issued during the nine months ended September 30, 2012 was \$0.65.

As of September 30, 2012, there was approximately \$1,800,000 of total unrecognized compensation expense related to unvested stock options under the Plan. That expense is expected to be recognized over the weighted-average remaining vesting period of 1.42 years.

#### **Other Stock Based Compensation**

As additional compensation to Dr. Kammer under his Advisory Agreement, Dr. Kammer is to be compensated \$10,000 per month in the form of common stock issued outside of the Plan, based on a \$0.90 price per share being allocated to each dollar of payment due to Dr. Kammer. Upon the completion of a financing transaction yielding not less than \$15 million to the Company, Dr. Kammer may unilaterally choose to be paid in either cash or common stock, based on the same \$0.90 price per share. Dr. Kammer and the Company have agreed that the common stock issuable to Dr. Kammer as compensation under his advisory agreement is to be accrued and issued on a quarterly or annual basis; accordingly, as of the date hereof no such shares have been issued to Dr. Kammer. The balance due to Dr. Kammer at September 30, 2012 under the Advisory Agreement was \$71,667 (share equivalent of 66,667 common shares) and is included in accounts payable and accrued expenses in the accompanying unaudited condensed consolidated balance sheet.

## NOTE 5. WARRANTS

On April 25, 2012, at the closing of the April Private Placement (see Note 4), the Company issued warrants to certain accredited investors to purchase up to an aggregate amount of 2,514,642 shares of common stock with an exercise price of \$1.185. The warrants have an initial exercise date of April 25, 2012 and a three-year term. Also on April 25, 2012, in connection with the Conversion Agreement (see Note 3) between the Company and DermaStar, a related party, the Company issued to DermaStar a warrant to purchase up to 241,308 shares of the Company's common stock with an exercise price of \$1.185 per share. The warrant has an initial exercise date of April 25, 2012 and a three-year term.

The warrants issued as part of the April Private Placement and to DermaStar have mandatory exercise provisions providing that the Company may require the holders of the warrants to exercise the warrants in full but not in part within twenty (20) business days after the date of a written notice delivered by the Company to each holder of a warrant; provided that (i) the value weighted average price of the Company's common stock for ten (10) consecutive trading days is equal to or greater than the exercise price, (ii) the Company has received a Filing Review Notification (commonly referred to as a "74 Day Letter") from the U.S. Food and Drug Administration regarding the status of the Company's Impracor topical non-steroidal anti-inflammatory drug, and (iii) sufficient shares of the Company's common stock are authorized and reserved for issuance upon full exercise of the warrants.

A summary of the activity of the warrants for the nine months ended September 30, 2012 is as follows:

	Number of Shares Subject to Warrants Outstanding	ghted Avg. reise Price
Warrants outstanding – January 1, 2012	95,498	\$ 33.16
Granted	2,755,950	1.19
Exercised	-	
Expired	(64,745)	32.00
Warrants outstanding and exercisable - September 30, 2012	2,786,703	\$ 1.56
Weighted average remaining contractual life of the outstanding warrants in years - September 30, 2012	2.55	

#### NOTE 6. COMMITMENTS AND CONTINGENCIES

#### Commitments

The Company leases its office facilities under a noncancelable operating lease, which expires on February 28, 2014, with a monthly amount due of \$2,972 for the first 12 months beginning March 1, 2012, and \$3,715 due monthly for the next 12 months. For the remaining fiscal year 2012, the Company's lease commitment is approximately \$8,900.

#### **Indemnities and Guarantees**

In addition to the indemnification provisions contained in the Company's charter documents, the Company generally enters into separate indemnification agreements with the Company's directors and officers. These agreements require the Company, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as the Company's director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by the Company. These guarantees and indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically, the Company has not been obligated nor incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities and guarantees in the accompanying condensed consolidated balance sheets.

#### **PCCA License Agreement**

Pursuant to the terms of the PCCA License Agreement entered in connection with the PCCA Transaction (Note 4), effective August 30, 2012, PCCA has granted to the Company and its affiliates certain exclusive rights under PCCA's proprietary formulations, other technologies and data, and the Company has agreed to pay to PCCA certain royalties on net sales relating to the sale of certain future products, which royalties range from 4.5% to 9% for each product, subject to certain minimum royalty payments. PCCA may terminate the PCCA License Agreement if the Company fails to commence efforts to research and develop future products within certain time periods, as set forth in the PCCA License Agreement.

#### **Cosmetic License Agreements - Terminated**

On May 20, 2009, the Company and JH Direct, LLC ("JH Direct") entered into a licensing agreement providing JH Direct with the exclusive worldwide rights to the Company's anti-cellulite cosmetic product which utilizes the Company's patented transdermal delivery system technology, Accudel. Under the terms of the agreement, JH Direct must pay the Company initial royalty advances and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. The Company received non-refundable royalty advances totaling \$100,000 from JH Direct. During the nine months ended September 30, 2012, management of the Company concluded that JH Direct had abandoned its efforts to commercialize the anti-cellulite cream and the Company exercised its rights to terminate the agreement in January 2012, at which time all revenues from this agreement were recognized in full. The Company does not expect to receive any additional funds from JH Direct under this contract.



#### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Unaudited Condensed Consolidated Financial Statements and the related notes thereto contained in Part I, Item 1 of this Quarterly Report. The information contained in this Quarterly Report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Quarterly Report and in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and subsequent reports on Form 8-K, which discuss our business in greater detail. Unless the context indicates otherwise, the "Company", "we", "us", and "our" in this Item 2 and elsewhere in this report refer to Imprimis Pharmaceuticals, Inc., a Delaware corporation.

The following discussion contains forward-looking statements regarding future events and our future performance. These forward-looking statements involve risk and uncertainties that could cause actual results to differ materially from those expected or projected. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs and expenses, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words "anticipate," "believes," "estimates," "intends," "may," "plans," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements reflect our current views with respect to future events. We cannot guarantee that we actually will achieve the plans, intentions, or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the expressed or implied forward-looking statements we make. These important factors include our ability to successfully resume operations and implement our business plan following dismissal of the Chapter 11 Case; our ability to raise capital; the cost of any capital we are able to raise; our ability to hire, retain and otherwise engage qualified personnel to execute our business plan; the success of the design and execution of our clinical trials; our ability to research and successfully develop our product candidates; our ability to continue as a going concern; our limited operating history; the ability of competitors to access the market we intend to serve; the ongoing market need for the technologies and products we are developing; and the other risks and uncertainties described under the heading "Risk Factors" in Part II, Item 1A of this Quarterly Report and in similar discussions in our other SEC filings. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change. Readers should not rely on any of our forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

#### Overview

Imprimis Pharmaceuticals, Inc. is a specialty pharmaceutical company developing non-invasive, topically delivered products. Our innovative patented Accudel cream formulation technology is designed to enable highly targeted site specific treatment. Impracor, our lead pain product candidate, utilizes the Accudel platform technology to deliver the active drug, ketoprofen, a non-steroidal anti-inflammatory drug, through the skin directly into the underlying tissues where the drug exerts its localized anti-inflammatory and analgesic effects.

Through our strategic relationship with Professional Compounding Centers of America, Inc. ("PCCA"), one of the largest drug compounding organizations in the world, we expect to facilitate our future selection, formulation and development of potential product candidates. Our relationship with PCCA is exclusive and provides us with the opportunity to develop new products using PCCA's proprietary drug formulations and drug delivery technologies, as well as access to an extensive database of market-oriented information related to a specific drug development opportunity. We plan to use our proprietary Accudel drug delivery technology, coupled with these licensed technologies, formulations and market data, to identify pharmaceutical development opportunities where we perceive a significant unmet need for a new drug product. We are currently considering potential product candidates in the muscle relaxant and neuropathic pain fields, and we expect those areas may be our next avenues for additional product development.

On February 28, 2012, we changed our name from Transdel Pharmaceuticals, Inc. to Imprimis Pharmaceuticals, Inc. Also on February 28, 2012, we effected a one-for-eight reverse split of our issued and outstanding common stock. The information in this report and the accompanying condensed consolidated financial statements have been retroactively adjusted to reflect the effects of the one-for-eight reverse stock split.

We have incurred recurring operating losses, have had negative operating cash flows and have not recognized any significant revenues since July 24, 1998 (inception). In addition, we have a deficit accumulated during the development stage of approximately \$22.7 million at September 30, 2012. We have not yet generated commercial sales revenue from any of our product candidates and we will incur further losses through the 2012 fiscal year and beyond as we continue the clinical development of our drug candidates, including Impracor, and conduct preclinical studies on other programs. Our research and development activities are budgeted to expand over time, and will require further capital resources to fund the continued operation of our business model for a long enough period to achieve profitable operations.

#### **Plan of Operations**

For the next twelve months, our current operating plan is focused on the development of our lead product candidate, Impracor, for the indication of acute musculoskeletal pain, inflammation and swelling associated with soft tissue injuries, and limited development of other potential product candidates and pursuit of co-development opportunities in other therapeutic areas, in each case utilizing our Accudel platform technology.

On June 26, 2011 we filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the "Bankruptcy Court"), Case No. 11-10497-11 (the "Chapter 11 Case"). Following the filing of the Chapter 11 Case with the Bankruptcy Court, we suspended our operations and terminated nearly all of our employees. Since the dismissal of the Chapter 11 Case in December 2011, as further described below, we have engaged a new management team, appointed new directors to fill certain vacancies on our Board and worked towards re-initiating our Phase 3 clinical trials for Impracor. However, we have a limited operating history since the dismissal of the Chapter 11 Case, and we may not be successful in our efforts to resume our operations. Prior to the filing of the Chapter 11 Case, we were unable to successfully pursue our business plan and continue our clinical trials due to a lack of funding. Given our operating history, we may be unable to obtain additional funds, when necessary, maintain an effective management team, or hire and retain further qualified individuals. As a result, we may be unable to successfully pursue our business plan.

#### **Clinical Program for Impracor**

For Impracor to be approved by the U.S. Food and Drug Administration (the "FDA"), an additional two confirmatory Phase 3 trials with exposure of at least 300 to 500 patients and supportive dermal safety studies are required. In September 2012, as required by the FDA, we began routine supportive trials in healthy patients to study the absorption (blood levels) of ketoprofen during concurrent exercise and heat exposure, as well as the relative bioavailability of Impracor or topical ketoprofen versus oral ketoprofen. We expect that all clinical studies will be executed with the professional help of clinical research organizations ("CROs") with experience in clinical trials of similar design. We are in the process of selecting and negotiating arrangements with potential CROs and other third parties in order to initiate our Phase 3 clinical trials.

We plan to commence two Phase 3 studies of Impracor in patients experiencing pain from osteoarthritis flare in their knees. The FDA has indicated that the osteoarthritis flare study design is an acceptable clinical model of acute pain. The Phase 3 program is being planned to encompass two double-blind placebo controlled Phase 3 osteoarthritis flare trials in approximately 330 to 360 patients each in 35 to 50 sites throughout the United States. Following an NSAID wash-out period, the proposed design study has the patients dosed with placebo or Impracor three times daily for 14 days. The primary endpoint for both trials is expected to employ well accepted pain measurements, which will be measured on day 7. It is expected that the planned trials, if successful, would provide sufficient evidence of efficacy and safety data for subsequent filing of a New Drug Application ("NDA") with the FDA.

Following successful completion of our clinical trials, we plan to file a NDA for marketing authorization for Impracor under Section 505(b)(2) of the Hatch-Waxman Act of 1984, a regulatory route towards FDA approval, which allows referencing our submission to previously established safety and/or effectiveness of already approved ketoprofen products in other dosage forms. We believe that this route provides the most attractive path for Impracor to reach the market.

The timing of Phase 3 trials and the other supportive studies will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures, as well as feedback from the FDA. We began certain supportive studies in September 2012 and, subject to the availability of sufficient funding, we intend to commence Phase 3 trials in early 2013. Assuming successful completion and outcome of the additional Phase 3 trials, we would expect to file a NDA for Impracor in 2014.

We expect that Impracor, if approved by the FDA, could become one of the first NSAID cream products available by prescription in the United States for the topical treatment of acute musculoskeletal pain.

#### **Product Development Program**

We believe that the clinical success of Impracor will facilitate the use of the Accudel delivery technology in other products. We have identified development opportunities for potential products in pain management and other therapeutic areas utilizing the Accudel platform technology and we are exploring potential commercial relationships for these identified product candidates. In particular, we are currently considering potential new drug candidates in the muscle relaxant and neuropathic pain fields, and we expect those to be our next avenues for new product development. We estimate that pre-Phase 3 clinical studies for these two potential product candidates could each be completed approximately 18 to 24 months after their commencement, and that costs for such development would range from approximately \$2 million to \$2.5 million for each proposed drug candidate.

In addition, we expect our new relationship with PCCA to facilitate our future selection, development and formulation of potential product candidates. We plan to use our proprietary Accudel drug delivery technology, coupled with these licensed technologies, formulations and market data, to identify pharmaceutical development opportunities where there is a significant unmet need for a new drug product. We are currently considering potential product candidates in the muscle relaxant and neuropathic pain fields, and we expect those areas may be our next avenues for additional product development.

In the past our product development program has included cosmetic and cosmeceutical products utilizing our patented transdermal delivery system technology, Accudel. Our lead product candidate was an anti-cellulite formulation, for which we have initial clinical information supporting the beneficial effects of this cosmetic product on skin appearance. Our potential pipeline of cosmetic products includes hyperpigmentation and anti-aging formulations. We remain interested in pursuing this business opportunity and continue to consider entering into new relationships with third parties. We may also pursue the out-licensing of our Accudel drug delivery technology for the development and commercialization of additional innovative drug and cosmeceutical products.

#### **Recent Developments**

#### Bankruptcy Petition and Dismissal

On June 26, 2011 we filed the Chapter 11 Case with the Bankruptcy Court. In connection with the Chapter 11 Case, we, as seller, and Cardium Healthcare, Inc., a wholly-owned subsidiary of Cardium Therapeutics, Inc., as purchaser ("Cardium"), entered into an Asset Purchase Agreement dated June 23, 2011 (the "Asset Purchase Agreement") pursuant to which we agreed to sell substantially all of our assets pursuant to Sections 105, 363 and 365 of the Bankruptcy Code, subject to court approval and the satisfaction of certain conditions set forth in the Asset Purchase Agreement. Consummation of the sale to Cardium was subject to a number of conditions, including, among others, the approval by the Bankruptcy Court of the transactions contemplated by the Asset Purchase Agreement and compliance with certain specified deadlines for actions in connection with the Chapter 11 Case. The Asset Purchase Agreement was terminable by the parties under a number of circumstances, including failure to obtain certain Bankruptcy Court orders by agreed dates.

On July 26, 2011, the Bankruptcy Court denied our motion to sell our assets pursuant to the Asset Purchase Agreement. On October 7, 2011, we terminated the Asset Purchase Agreement pursuant to its terms. On November 21, 2011, in connection with the transactions described below, we requested that the Bankruptcy Court dismiss the Chapter 11 Case and retain jurisdiction to decide matters related to claims brought in the Chapter 11 Case by Cardium. On December 8, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case. In connection with the dismissal of the Chapter 11 Case, the Bankruptcy Court, among other things, declined to retain jurisdiction over claim objection proceedings and found moot our objection to certain claims of Cardium. The dismissal of the Chapter 11 Case was based upon the provisions of both 11 U.S.C. Sections 305(a) and 1112(b).

#### Secured Line of Credit

On November 21, 2011, we entered into a Secured Line of Credit Letter Agreement (the "Line of Credit Agreement") with DermaStar International, LLC ("DermaStar"), pursuant to which DermaStar agreed to lend us funds under a line of credit upon certain conditions, including the dismissal of the Chapter 11 Case by the Bankruptcy Court. The Line of Credit Agreement became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. The Line of Credit Agreement provided for advances of up to an aggregate of \$750,000, subject to the satisfaction by us of certain conditions in connection with the initial advance and each subsequent advance.

On April 25, 2012, the entire outstanding principal balance and all accrued and unpaid interest under the line of credit, an aggregate of \$762,534, was converted into 965,233 shares of common stock and warrants to purchase 241,308 shares of common stock at the offering price and on the terms of the April Private Placement (as defined and described below), pursuant to the terms of a conversion agreement we entered into with DermaStar on April 20, 2012. The warrants have substantially the same terms as the warrants issued in the April Private Placement. The line of credit was terminated upon the completion of the conversion.

#### Change in Control – Issuance of Preferred Stock

In partial consideration for and in connection with the Line of Credit Agreement, on November 21, 2011 we executed a Securities Purchase Agreement (the "Series A Purchase Agreement") with DermaStar, pursuant to which we agreed to issue 10 shares of newly-designated Series A Convertible Preferred Stock (the "Series A Preferred Stock") to DermaStar for an aggregate purchase price of \$100,000. The Series A Purchase Agreement, as amended, became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court on December 8, 2011. On December 12, 2011, we and DermaStar consummated the transactions contemplated by the Series A Purchase Agreement. The shares of Series A Preferred Stock issued to DermaStar in the offering were convertible into 7,498,500 shares of our common stock. Upon issuance of the Series A Preferred Stock, DermaStar, and its members individually, became control persons of the Company. We appointed DermaStar Managing Members Mark L. Baum and Robert J. Kammer to our Board of Directors in December 2011.

On June 29, 2012, DermaStar converted the 10 shares of Series A Preferred Stock held by it into 7,498,500 shares of our common stock. In connection with the conversion, we paid to DermaStar \$200,000 as partial consideration for the conversion pursuant to a conversion agreement. Immediately following the conversion of the Series A Preferred Stock, all 10 shares were retired to our treasury and cancelled. The conversion agreement was unanimously approved by the Company's disinterested directors, with Mr. Baum and Dr. Kammer abstaining.

#### Settlement with the Holders of the Company's 7.5% Convertible Promissory Note

On April 5, 2010, we issued a \$1,000,000 7.5% Convertible Promissory Note (the "Convertible Note") to Alexej Ladonnikov. During January 2012, Mr. Ladonnikov sold 80% of the Convertible Note to DermaStar in a private transaction. Effective as of January 25, 2012, we entered into separate waiver and settlement agreements with DermaStar and Mr. Ladonnikov. Under each of the waiver and settlement agreements, the holders of the Convertible Note agreed to forever waive (i) their rights to accelerate the entire unpaid principal sum of the Convertible Note and all accrued interest pursuant to Section 1 of the Convertible Note, (ii) their rights under Section 7 of the Senior Convertible Note Purchase Agreement dated April 5, 2010, and (iii) certain conversion rights pursuant to Section 3 of the Convertible Note. Under the terms of the waiver and settlement agreement with DermaStar, we and DermaStar agreed to the mandatory conversion of the principal and accrued and unpaid interest of the Convertible Note and \$56,087 in current accounts payable of the Company held by DermaStar into our common stock at a conversion price of approximately \$0.13336 per share at such time as we had a sufficient number of shares of authorized common stock to effect such conversion. Under the terms of the waiver and settlement agreement with Mr. Ladonnikov, we and Mr. Ladonnikov agreed to the mandatory conversion of the 20% of the principal and accrued and unpaid interest of the Convertible Note held by Mr. Ladonnikov, at such time as we had a sufficient number of authorized common shares to effect such a conversion, into our common stock at a conversion shares to effect such a conversion, into our common stock at a conversion price of \$50,000 to us at such time as the Convertible Note was converted into common stock.

On February 28, 2012, effective immediately following the effective time of our Certificate of Amendment to our Certificate of Incorporation increasing the number of authorized shares of common stock and implementing the one-for-eight reverse split of our common stock, the entire outstanding balance and all accrued but unpaid interest owing under the Convertible Note and the accounts payable held by DermaStar were converted into 9,179,150 shares of common stock, and the Convertible Note was terminated. Mr. Ladonnikov made the required one-time payment of \$50,000 to us at the time of the conversion.

#### Changes in Management and Board of Directors

As a result of the Chapter 11 Case, our management team has undergone significant changes. The Board accepted the resignation of John N. Bonfiglio, Ph.D. as our Chief Executive Officer and President, effective May 13, 2011. On the same date, the Board appointed John T. Lomoro to serve as the Company's Principal Executive Officer. Effective September 16, 2011, the Board accepted the resignation of John T. Lomoro as Principal Executive Officer, Chief Financial Officer and Treasurer of the Company. On the same date, the Board appointed Terry Nida, the Company's Chief Business Officer, to serve as the Company's Principal Executive Officer and Principal Financial Officer. Effective December 16, 2011, Terry Nida resigned as Principal Executive Officer and Principal Financial Officer of the Company.

In January 2012, we began assembling a new management team. Effective January 1, 2012, the Board appointed Balbir Brar, D.V.M., Ph.D. as President of the Company. Effective February 1, 2012, the Board appointed Andrew R. Boll as Vice-President of Accounting and Public Reporting and Principal Accounting and Financial Officer of the Company. Effective February 15, 2012, the Board appointed Joachim Schupp, M.D. as Chief Medical Officer of the Company. Dr. Schupp had previously served as our Chief Medical Officer and Dr. Brar had previously served as our Vice President of Research and Development. Mr. Baum served as our Chairman of the Board of Directors and principal executive officer beginning in December 2011. On April 1, 2012, the Board appointed Mr. Baum as our Chief Executive Officer and Mr. Baum stepped down as our Chairman of the Board. He continues to serve as a director.



Our Board of Directors has also undergone significant change. Effective December 16, 2011, Anthony S. Thornley resigned from our Board of Directors, and Mr. Baum and Dr. Kammer, managing members of DermaStar, joined the Board of Directors. Effective February 15, 2012, Paul Finnegan, M.D. and Dr. Brar, our President, were appointed as directors of the Company. On April 1, 2012, Dr. Kammer began serving as the Chairman of the Board of Directors. On July 26, 2012, Stephen Austin, CPA, was appointed as a director of the Company and Dr. Brar, who continues to serve as our President, resigned as a director. We currently have five directors, as follows: Jeffrey Abrams, M.D., Mr. Austin, Mr. Baum, Dr. Kammer and Dr. Finnegan.

#### April Private Placement

On April 20, 2012, we entered into a Securities Purchase Agreement with certain accredited investors relating to the sale and issuance of an aggregate of 10,058,455 shares of our common stock and warrants to purchase up to 2,514,642 shares of common stock at an exercise price of \$1.185 per share, for an aggregate gross purchase price of approximately \$7.95 million (the "April Private Placement"). We closed the April Private Placement on April 25, 2012. The securities sold in the April Private Placement were sold in reliance on the exemption from the registration requirements of the Securities Act of 1933 (the "Securities Act") afforded by Section 4(2) of the Securities Act and Rule 506 of Regulation D.

The investors are not entitled to any registration rights with respect to the common stock and warrants issued in the April Private Placement. The warrants have a term of three years and are exercisable any time after April 25, 2012. We may require that the investors exercise the warrants in whole, but not in part, at any time within 20 business days after all of the following conditions have been satisfied: (i) the volume weighted average price of the our common stock for 10 consecutive trading days is equal to or greater than the exercise price of the warrants; (ii) we have received a Filing Review Notification from the FDA regarding the status of Impracor; and (iii) sufficient shares of common stock are authorized and reserved for issuance upon full exercise of the warrants.

#### PCCA Transaction

On August 30, 2012, we entered into a License Agreement (the "PCCA License Agreement") and a Stock Purchase Agreement (the "PCCA Purchase Agreement") in a strategic transaction with PCCA (the "PCCA Transaction").

Pursuant to the terms of the PCCA License Agreement, effective August 30, 2012, PCCA has granted to us and our affiliates certain exclusive rights under PCCA's proprietary formulations, other technologies and data, and we have agreed to pay to PCCA certain royalties on net sales relating to the sale of certain future products, which royalties range from 4.5% to 9% for each product, subject to certain minimum royalty payments. PCCA may terminate the PCCA License Agreement if we fail to commence efforts to research and develop future products within certain time periods.

Pursuant to the terms of the PCCA Purchase Agreement, closed on August 31, 2012, we issued and sold to PCCA 4,163,414 shares of our common stock at a per share purchase price of \$0.96075, for aggregate gross proceeds to us of \$4,000,000. The PCCA Purchase Agreement does not grant to PCCA any registration rights with respect to the shares purchased and sold thereunder. The shares sold to PCCA were sold in reliance on the exemption from the registration requirements of the Securities Act afforded by Section 4(2) thereof.

#### **Results of Operations**

The following period to period comparisons of our financial results and our interim results are not necessarily indicative of future results.

#### For the Three and Nine Months Ended September 30, 2012, Compared to the Three and Nine Months Ended September 30, 2011

#### Revenues

No revenues were recognized during the three months ended September 30, 2012 and 2011. For the nine months ended September 30, 2012 we recognized \$100,000 in revenues, compared to no revenues recognized during the same period in the prior year. These revenues were non-refundable royalty advances, unrelated to product sales, paid to the Company in December 2010 and April 2011. The revenues stem from our terminated license agreement which had provided JH Direct rights to our anti-cellulite cosmetic product. This agreement was terminated in January 2012, and we do not expect any other revenues to be recognized from it.



#### Selling, General and Administrative Expenses

Our selling, general and administrative expenses include personnel costs including wages and stock-based compensation, corporate facility expenses, investor relations, consulting, insurance, legal and accounting expenses.

The table below provides information regarding selling, general and administrative expenses.

	Tł	ree months end	led Sep	otember 30,	\$	Nine months end	ed Sep	tember 30,	\$
		2012		2011	 Variance	 2012	_	2011	 Variance
Selling, general and administrative	\$	946,381	\$	66,496	\$ 879,885	\$ 2,240,004	\$	514,529	\$ 1,725,475

For the three and nine months ended September 30, 2012, there was an increase of \$879,885 and \$1,725,475, respectively, in selling, general and administrative expenses, as compared to the same periods in the prior year. The increase in selling, general and administrative expenses is largely attributable to the resumption of our operations in December 2011, following the winding down and ceasing operations during these periods in 2011, including the suspension of payroll beginning in March 2011. Selling, general and administrative expenses during the three and nine months ended September 30, 2012 were primarily due to the hiring of new personnel, consultants and management, legal and accounting fees associated with complying with our SEC reporting obligations and fees and expenses related to financing activities. A significant portion of the increase in personnel costs is associated with stock-based compensation for the three and nine months ended September 30, 2012, which increased \$194,685 and \$1,246,961, respectively, as compared to the same periods in the prior year.

#### **Research and Development Expenses**

Our research and development expenses primarily include expenses related to the Impracor clinical program. These costs are comprised of expenses for our first Phase 3 study, including costs for our contract research organization and investigator payments to the clinical sites participating in the study. Other expenses are personnel costs including wages and stock-based compensation, contract manufacturing, non-clinical studies, consulting and other costs related to the clinical program.

The table below provides information regarding research and development expenses.

	Three months ended September 30,				_	\$	Ni	Nine months ended September 30,				\$	
	201	12		2011	_	 Variance		2012		2011		Variance	
Research and development	\$	303,666	\$		0	\$ 303,666	\$	580,240	\$	111,554	\$	468,686	

For the three and nine months ended September 30, 2012, there was an increase of \$303,666 and \$468,686, respectively, in research and development expense as compared to the same periods in the prior year. The increase was primarily related to the hiring of new personnel and consultants in 2012 for the planning and development of additional Phase 3 studies of our Impracor clinical program, and costs related to supportive safety studies for Impracor, which began in September 2012. A significant portion of the increase in research and development personnel costs is associated with stock-based compensation for the three and nine months ended September 30, 2012, which increased \$61,299 and \$105,957, respectively, as compared to the same periods in the prior year.

#### **Interest Expense**

Interest expense was \$0 and \$24,658 for the three and nine months ended September 30, 2012, respectively, compared to \$18,904 and \$56,095 for the three and nine months ended September 30, 2011, respectively. The 10% promissory notes issued under our Line of Credit Agreement with DermaStar accounted for \$0 and \$12,535 of interest expense during the three and nine months ended September 30, 2012, respectively, and \$0 during the same periods in the prior year. The 7.5% Convertible Note with a principal balance of \$1,000,000, issued in April 2010 (and converted to shares of our common stock in February 2012) accounted for \$0 and \$12,123 of interest expense during the three and nine months ended September 30, 2012, respectively, and \$18,904 and \$56,095 during the three and nine months ended September 30, 2012, respectively, and \$18,904 and \$56,095 during the three and nine months ended September 30, 2012, respectively, and \$18,904 and \$56,095 during the three and nine months ended September 30, 2012, respectively, and \$18,904 and \$56,095 during the three and nine months ended September 30, 2012, respectively, and \$18,904 and \$56,095 during the three and nine months ended September 30, 2011, respectively.

#### Loss on Extinguishment of Debt

Loss from extinguishment of debt was \$0 and \$1,195,410 for the three and nine months ended September 30, 2012, respectively. As further described above under the heading "Recent Developments", effective as of January 25, 2012, we entered into separate waiver and settlement agreements with DermaStar and Alexej Ladonnikov, the two holders of the Convertible Note. Pursuant to the waiver and settlement agreements, on February 28, 2012, the entire outstanding balance and all accrued but unpaid interest owing under the Convertible Note and the accounts payable held by DermaStar were converted into an aggregate of 9,179,150 shares of our common stock, and the Convertible Note was terminated. On February 28, 2012, we received payment from Mr. Ladonnikov of \$50,000 and issued 1,904,338 shares of common stock to Mr. Ladonnikov as payment in full for his 20% ownership of the Convertible Note (\$200,000) and its related accrued interest (\$28,521). We determined this to be a substantial modification to the debt instrument and applied debt extinguishment accounting to record a loss on extinguishment of debt of \$150,000 (\$200,000 Note principal balance less \$50,000 cash payment) for the nine months ended September 30, 2012. On February 28, 2012, we issued 7,274,812 shares of our common stock to DermaStar as payment in full for its 80% ownership of the Convertible Note (\$800,000), its related accrued interest (\$114,082) and \$56,087 in accounts payable. We determined this to be a substantial modification to the debt instrument and applied debt extinguishment accounting to record a loss on extinguishment accounting to record a loss of \$856,087 for the nine months ended September 30, 2012.

As further described above under the heading "Recent Developments", on April 20, 2012, DermaStar agreed to convert the promissory notes issued under the Line of Credit Agreement and their related accrued interest, totaling \$762,534, into 965,233 shares of our common stock and a related warrant to purchase up to an additional 241,308 shares of our common stock at an exercise price of \$1.185 per share. We determined this to be a substantial modification to the debt instrument and applied debt extinguishment accounting to record a loss on extinguishment of debt of \$189,323 for the nine months ended September 30, 2012.

#### Net Loss

Net losses attributable to common stockholders for the three and nine months ended September 30, 2012, were \$1,245,826 and \$4,130,507, respectively, or \$(0.04) and \$(0.22), respectively, per basic and diluted share, compared to net losses attributable to common stockholders for the three and nine months ended September 30, 2011 of \$85,400 and \$682,178, respectively, or \$(0.04) and \$(0.34), respectively, per basic and diluted share.

#### Liquidity and Capital Resources

Our cash on hand at September 30, 2012 was \$10,990,871 as compared to \$2,154 at September 30, 2011. The increase in cash on hand is primarily attributable to aggregate net proceeds of approximately \$11,916,000 received from our issuance of securities in the April Private Placement and the PCCA Transaction during the nine months ended September 30, 2012, and the \$750,000 drawn under our Line of Credit Agreement with DermaStar between December 2011 and April 2012. Since inception through September 30, 2012, we have incurred aggregate losses of approximately \$22,351,000. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for our lead drug, Impracor. Historically, our operations have been financed through capital contributions and debt and equity financings.

As further described under the heading "Recent Developments" above, on June 26, 2011, we filed a voluntary petition for reorganization relief under Chapter 11 of the U.S. Bankruptcy Code. Thereafter, we suspended our operations and terminated almost all of our employees. After receiving certain commitments from DermaStar to provide funding to us under a secured line of credit (as further described above under the heading "Recent Developments" and below), on November 21, 2011 we requested that the Bankruptcy Court dismiss the Chapter 11 Case. The Bankruptcy Court entered an order dismissing the Chapter 11 Case on December 8, 2011. Since December 9, 2011, we have focused on resuming the operation of our business, including assembling a management team and hiring employees.

#### **Convertible** Note

As further described above under the heading "Recent Developments," on April 5, 2010 we issued a \$1,000,000 7.5% Convertible Promissory Note. Effective as of January 25, 2012, we entered into separate waiver and settlement agreements with DermaStar and Alexej Ladonnikov, the two holders of the Convertible Note. Pursuant to the waiver and settlement agreements, on February 28, 2012, the entire outstanding balance and all accrued but unpaid interest owing under the Convertible Note and \$56,087 in accounts payable held by DermaStar were converted into 9,179,150 shares of common stock, and the Convertible Note was terminated. In addition, Mr. Ladonnikov made a one-time payment of \$50,000 to us at the time of the conversion.



#### Line of Credit

As further described above under the heading "Recent Developments," on November 21, 2011 we entered into the Line of Credit Agreement with DermaStar. The Line of Credit Agreement provided for advances of up to an aggregate of \$750,000, subject to the satisfaction by us of certain conditions in connection with each advance. Interest under the line of credit accrued at 10% per annum. As of December 31, 2011 and up to April 25, 2012 (the date of the conversion thereof), we had requested advances of \$300,000 and \$750,000, respectively, under the line of credit. On April 25, 2012, the entire outstanding principal balance and all accrued and unpaid interest under the line of credit, an aggregate of \$762,534, was converted into 965,233 shares of common stock and warrants to purchase 241,308 shares of our common stock. The line of credit was terminated upon the completion of the conversion.

#### April Private Placement

As further described above under the heading "Recent Developments," on April 25, 2012 we closed a private placement of securities with certain accredited investors for the sale and issuance of 10,058,455 shares of common stock and warrants to purchase up to 2,514,642 shares of common stock at an exercise price of \$1.185 per share, for aggregate proceeds, net of offering costs, to us of approximately \$7,930,000.

# **PCCA** Transaction

Pursuant to the terms of the PCCA Purchase Agreement that we entered into with PCCA in connection with the PCCA Transaction, on August 31, 2012, we issued and sold to PCCA 4,163,414 shares of our common stock at a per share purchase price of \$0.96075, for aggregate net proceeds to us of approximately \$3,980,000.

The table below provides detailed information about our net cash flow for the nine months ended September 30, 2012 and 2011.

Cash Flow	Nine Months E September	
	2012	2011
Net cash used in operating activities	\$ (1,287,127) \$	(316,845)
Net cash used in investing activities	(15,308)	-
Net cash provided by financing activities	12,147,146	27,537
Net Increase (Decrease) in Cash and Cash Equivalents	10,844,711	(289,308)
Cash and Cash Equivalents at Beginning of the Period	146,160	291,462
Cash and Cash Equivalents at End of the Period	\$ 10,990,871 \$	2,154

# **Operating Activities**

Net cash used in operating activities was \$1,287,127 for the nine months ended September 30, 2012, as compared to \$316,845 used in operating activities during the same period for the prior year. The increase in net cash used in operating activities was mainly due to resuming the operation of our business, including assembling a management team and hiring employees, planning and development of additional Phase 3 studies and the reduction of our historical working capital debt.

#### **Investing Activities**

Net cash used in investing activities for the nine months ended September 30, 2012 and 2011 was \$15,308 and \$0, respectively. The increase in investing activities during the nine months ended September 30, 2012 was due primarily to our move into our new office space and our acquisition of furniture and office equipment to furnish that office space.

#### **Financing Activities**

Net cash provided by financing activities for the nine months ended September 30, 2012 and 2011 was \$12,147,146 and \$27,537, respectively. The increase in cash is primarily attributable to aggregate proceeds, net of offering costs, of approximately \$7,930,000 received from the April Private Placement, \$3,980,000 from the PCCA Purchase Agreement, and the \$450,000 drawn under our Line of Credit Agreement with DermaStar between January 2012 and April 2012.

We expect to use our current cash position to begin executing on our business plan, including starting additional clinical studies related to our Accudel technology, and otherwise fund our operations. Management believes we have sufficient cash reserves to execute our business plan for the next twelve months. If we are not able to generate significant revenues and attain profitable operations, we will need to seek additional financing, including equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. In addition, estimates of our operating expenses and working capital requirements could be incorrect, and we could be required to seek additional financing earlier than we anticipate.

We will require additional funds in order to fully conduct our planned clinical trials and any other studies that may be required to obtain regulatory approval to market Impracor, to pursue additional pharmaceutical development programs and to explore other co-development opportunities. If adequate financing is not available, we may not be able to obtain regulatory approval to market Impracor or develop any additional products. We may seek funds from equity or debt financings, a corporate partnership or licensing arrangement (as we did with the PCCA Transaction), or any other similar financing. Any future financings through equity investments are likely to be dilutive to existing stockholders. Also, the terms of securities we may issue in future capital transactions may be more favorable for our new investors. Newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial results.

We may be unable to obtain financing when necessary as a result of, among other things, general economic conditions, conditions in the pharmaceuticals industry or as a result of our operating history, including our recent bankruptcy proceedings. In addition, the fact that we are not and have never been profitable and will require additional funds to complete our planned clinical trials could further impact the availability or cost of future financings. There is no assurance that sufficient financing will be available to us, or, if available, will be on terms that would be acceptable to us. If we are unable to raise funds to satisfy our capital needs on a timely basis, then we may not be able to obtain regulatory approval to market Impracor or develop any additional products or otherwise pursue our business plan, and we may be required to cease operations.

As reported in the Report of Independent Registered Public Accounting Firm on our December 31, 2011 consolidated financial statements, we have incurred recurring losses from operations and have an accumulated deficit that raised substantial doubt about our ability to continue as a going concern. At September 30, 2012, the Company had increased its cash position by approximately \$11 million as compared to our cash position at December 31, 2011. As of the date of this Quarterly Report, management believes we have sufficient cash reserves to support our operating plan and fund operating cash flow requirements through the next twelve months.

#### **Critical Accounting Policies**

We rely on the use of estimates and make assumptions that impact our financial condition and results. These estimates and assumptions are based on historical results and trends as well as our forecasts as to how results and trends might change in the future. Although we believe that the estimates we use are reasonable, actual results could differ from those estimates.

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve more significant judgments and estimates used in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and any changes in the different estimates that could have been used in the accounting estimates that are reasonably likely to occur periodically could materially impact our condensed consolidated financial statements.



Our most critical accounting policies and estimates that may materially impact our results of operations include:

Stock-Based Compensation. All share-based payments to employees, including grants of employee stock options and restricted stock grants, to be recognized in the consolidated financial statements are based upon their fair values. We use the Black-Scholes-Merton option pricing model to estimate the grant-date fair value of share-based awards. Fair value is determined at the date of grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates.

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows Financial Accounting Standards Board ("FASB") guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during the vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is recognized over the term of the consulting agreement. An asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, we record the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in our condensed consolidated balance sheets.

*Income Taxes.* As part of the process of preparing our consolidated financial statements, we must estimate our actual current tax liabilities together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within the balance sheet. We must assess the likelihood that the deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, a valuation allowance must be established. To the extent we establish a valuation allowance or increase or decrease this allowance in a period, the impact will be included in the tax provision in the statement of operations.

Research and Development. We expense all costs related to research and development as they are incurred.

#### **Off-Balance Sheet Arrangements**

Since our inception, except for standard operating leases we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities. We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to stockholders.

#### **Recent Accounting Pronouncements**

There are no recent accounting pronouncements issued by the FASB that management believes have had or are reasonably likely to have a material impact on our present or future condensed consolidated financial statements.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

#### ITEM 4. CONTROLS AND PROCEDURES.

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

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information that would be required to be disclosed in Exchange Act reports is recorded, processed, summarized and reported within the time period specified in the rules and forms of the Securities and Exchange Commission (the "SEC"), and that such information is accumulated and communicated to our management, including to our principal executive officer and principal accounting and financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, as of September 30, 2012. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2012, our disclosure controls and procedures were not effective because of the existence of unremediated material weaknesses, as described in Item 9A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

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

During the third quarter of fiscal 2012, we continued to pursue certain actions to remediate material weaknesses in our internal control over financial reporting described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. We have begun to implement, or expect to implement, the following corrective actions during the year ending December 31, 2012:

- Our Board of Directors has established an Audit Committee, comprised of independent directors. On July 26, 2012, we appointed Stephen Austin, CPA, to our Board of Directors. The Board has determined that Mr. Austin is a "financial expert," as the SEC has defined that term in Item 407 of Regulation S-K. Mr. Austin serves on the Audit Committee as its chairman. The Audit Committee operates independently of our Board of Directors as contemplated by the charter for that committee, and is tasked with, among other things, oversight of selection of our independent registered public accounting firm and the audit of our financial statements.
- We are in the process of adopting and implementing procedures designed to ensure better coordination, oversight and communication among our finance, human resources, and legal functions to ensure that no one person or department would have complete control in the accounting and financial reporting process. We have hired qualified consultants to assist us in the remediation of our material weaknesses, and implementation of effective controls following the guidance issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO.

As of the date of this Quarterly Report, our remediation efforts continue related to each of the material weaknesses described in our Annual Report on Form 10-K for the year ended December 31, 2011. Those material weaknesses will not be considered remediated until (1) the procedures described above have been designed, appropriately controlled and implemented for a sufficient period of time, and (2) we have sufficient evidence that those procedures and related controls are operating effectively.

Other than our ongoing remediation efforts described above, there have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 1. LEGAL PROCEEDINGS**

We are not aware of any pending legal proceedings to which we are a party or of which any of our property is subject the adverse outcome of which, individually or in the aggregate, would have a material adverse effect on our financial position or results of operations.

#### **ITEM 1A. RISK FACTORS**

You should carefully consider the following risk factors in addition to the other information contained in this report and our other filings with the SEC. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also impair our business financial condition, results of operations and stock price. This Quarterly Report contains forward-looking statements.

#### **Risks Related to Our Business**

# We have a limited operating history since the dismissal of our voluntary petition for reorganization relief under Chapter 11 of the Bankruptcy Code in December 2011, and we may be unable to successfully resume our operations and implement our business plan.

On June 26, 2011, we suspended our operations and filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Court for the Southern District of California (the "Bankruptcy Court"), Case No. 11-10497-11 (the "Chapter 11 Case"). On November 21, 2011, in connection with our entry into a line of credit agreement and securities purchase agreement with DermaStar International, LLC ("DermaStar"), we requested that the Bankruptcy Court dismiss the Chapter 11 Case. On December 8, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case, and since that date we have engaged a new management team, appointed new directors to fill certain vacancies on our Board and worked towards re-initiating our Phase 3 clinical trials for Impracor. However, we have a limited operating history since the dismissal of the Chapter 11 Case, and we may not be successful in our efforts to resume our operations. We did not receive any type of discharge of debts, claims or obligations in the Chapter 11 Case, and prior unknown or contingent liabilities could have a material adverse effect on our financial condition. Prior to the filing of the Chapter 11 Case, we were unable to successfully pursue our business plan due to a lack of funding. We will require additional capital to pursue our clinical trials and maintain our operations. We may be unable to obtain such funds when necessary. In addition, by September 2011 we employeed no full-time employees and had retained the consulting services of one former employee in order to manage any matters related to the Chapter 11 Case. We have had to re-assemble an executive management team and a research and development team, and other employees to assist with our general operations. We currently have five employees, a number of whom are former employees, and we will need to hire additional employees in order to execute our business plan. Given our operating history, we may be unable to maintain an effective management team, or hire and retain the

# We must raise additional capital in order to continue operating our business, and such additional funds may not be available on acceptable terms or at all.

Although we believe we have sufficient cash reserves to execute our business plan for the next twelve months, we must raise additional funds in order to continue operating our business and fully execute our business plans. We will likely need significant additional capital, which we may seek to raise through, among other things, public and private equity offerings and debt financing. If we are not able to generate significant revenues and attain profitable operations, we will need to continue to seek further additional financing. In addition, estimates of our operating expenses and working capital requirements could be incorrect, and we could be required to seek additional financing earlier than we anticipate. We expect to continue to fund our operations primarily through equity and debt financings in the future, and could also pursue finding from corporate partnerships or licensing arrangements (as we did with the PCCA Transaction) or similar financings. If additional capital is not available when necessary, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.



We expect our total expenditures over the next 12 months to be approximately \$9.3 million. However, our estimate of total expenditures could increase if we encounter unanticipated difficulties. In addition, our estimates of the amount of cash necessary to fund our business may prove to be wrong and we could spend our available financial resources much faster than we currently expect. If we do not have sufficient funds to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations. If any of these events were to occur, there is a substantial risk that our business would fail. Sources of additional funds may not be available on acceptable terms or at all. Weak economic and capital market conditions could result in increased difficulties in raising capital for our operations. We may not be able to raise money through the sale of our equity securities or through borrowing funds on terms we find acceptable, or at all. If we cannot raise the funds that we need, we will be unable to continue our operations, and our stockholders could lose their entire investment in our company.

If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

# We have incurred losses in the research and development of Impracor and our Accudel technology since inception. We may never generate revenue or become profitable.

We have incurred losses in every year of our operations, including net losses of (953,936) and (2,531,228) for the years ended December 31, 2011 and 2010, respectively. As of September 30, 2012, our accumulated deficit was (22,651,240). In addition, we expect to incur increasing operating losses for the foreseeable future as we continue to incur costs for research and development and clinical trials, and in other development activities. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products. Development is costly and requires significant investment. In addition, we may choose to in-license rights to particular drugs or active ingredients for use in cosmetic products. The license fees for such drugs or active ingredients may increase our costs.

As we continue to engage in the development of Impracor and develop other products, we may never be able to achieve or sustain market acceptance, profitability or positive cash flow. Our ultimate success will depend on many factors, including whether Impracor receives FDA approval. We cannot be certain that we will receive FDA approval for Impracor, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability. Unless we raise additional capital, we will not be able to execute our business plan or fund business operations. Furthermore, we will be forced to reduce our expenses and cash expenditures to a material extent, which would impair or delay our ability to execute our business plan.

#### We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the time and resources required to develop, conduct clinical trials and obtain regulatory approvals for our drug candidates;
- the costs to rebuild our management team following the dismissal of the Chapter 11 Case, including attracting and retaining personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

If our estimates of our operating expenses prove to be wrong, we could spend our available financial resources much faster than we currently expect. If we do not have sufficient funds to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations.

# The report of our independent registered public accounting firm on our 2011 consolidated financial statements contains a going concern modification, and we will need additional financing to execute our business plan, fund our operations and to continue as a going concern.

We have limited remaining funds to support our operations. We have prepared our consolidated financial statements for the fiscal year ended December 31, 2011 and the nine months ended September 30, 2012 on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The report of our independent registered public accounting firm included in our December 31, 2011 consolidated financial statements includes an explanatory paragraph stating that the recurring losses incurred from operations and a working capital deficiency raise substantial doubt about our ability to continue as a going concern. In the nine months ended September 30, 2012, we received approximate proceeds, net of related costs, of approximately \$7.93 million in the April Private Placement and \$3.98 million in connection with the PCCA Transaction. We expect to use those funds to pursue obtaining regulatory approval to market Impracor and pursue our business plan, but we will need to secure additional funds in order to complete our clinical trials and pursue other product development opportunities. As a result of such transactions and in light of our current cash and cash equivalents position as of the date of this report, we expect to have adequate resources in order to operate our business through the next twelve months. However, our auditors may have doubt about our ability to continue as a going concern in future periods, and our financial statements relating to those periods may not be prepared on a going-concern basis based on any such doubts. Further, even with our current cash position as a result of our recent financings, we will need to secure additional funds in order to complete our clinical trials and pursue other product development opportunities. If adequate financing is not available, we will not be able to meet FDA requirements to obtain regulatory approval to market Impracor. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise further additional funds sooner than anticipated. The inclusion of a going concern modification in our independent registered public accounting firm's report for the year ended December 31, 2011, or in any future report, may materially and adversely affect our stock price or our ability to raise new capital.

#### Our clinical trials may not demonstrate the safety and efficacy of our product candidates.

We are subject to extensive government regulations. The process of obtaining FDA approval is costly, time consuming, uncertain and subject to unanticipated delays. Before obtaining regulatory approvals for the sale of any of our product candidates, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of our product candidates. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals. Moreover, if the FDA grants regulatory approval of a product candidate, the approval may be limited to specific indications or limited with respect to its distribution, which could limit revenues.

The FDA or other regulatory agencies may not approve any product candidates developed by us on a timely basis or at all, and, if granted, such approval may subject the marketing of our product candidates to certain limits on indicated use. In particular, the outcome of the final analyses of the data from the Phase 3 clinical trials for Impracor may vary from our initial conclusions or the FDA may not agree with our interpretation of such results or may challenge the adequacy of our clinical trial design or the execution of the clinical trial. The FDA has required two adequate and well controlled Phase 3 clinical trials for Impracor before we can submit a New Drug Application under Section 505(b)(2) of the Hatch-Waxman Act of 1984. We have not yet initiated these Phase 3 clinical trials, although in September 2012 we commenced certain supportive studies relating to Impracor that are also required by the FDA. The results of any future clinical trials or studies may not be favorable and we may never receive regulatory approval for Impracor. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of product candidates developed by us would adversely affect our ability to generate product revenue, as well as the price of our common stock.

# Delays in the conduct or completion of our clinical and non-clinical trials for Impracor or the analysis of the data from our clinical or non-clinical trials may adversely affect our business.

We cannot predict whether we will encounter problems with any of our completed or planned clinical or non-clinical studies that will cause us or regulatory authorities to delay or suspend planned clinical and non-clinical studies. Any of the following could delay the completion of our planned clinical studies:

- failure of the FDA to approve the scope or design of our clinical or non-clinical trials or manufacturing plans;
- delays in enrolling volunteers in clinical trials;
- insufficient supply or deficient quality of materials necessary for the performance of clinical or non-clinical trials;
- negative results of clinical or non-clinical studies; and
- adverse side effects experienced by study participants in clinical trials relating to a specific product.
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There may be other circumstances other than the ones described above, over which we may have no control that could materially delay the successful completion of our clinical and non-clinical studies. Furthermore, we expect to rely on CROs to ensure the proper and timely conduct of our clinical trials, and while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

# If our patents are determined to be unenforceable or expire, or if we are unable to obtain new patents based on current patent applications or for future inventions, we may not be able to prevent others from using our intellectual property.

Our success will depend in part on our ability to:

- obtain and maintain patent protection with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur.

We obtained a patent from the United States Patent and Trademark Office on our Accudel technology in 1998, which affords protection of Accudel through 2016 in the United States. We may not be successful in our efforts to extend the date of our patent protection beyond 2016. Failure to maintain or extend the patent could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents cover them.

The patent and intellectual property positions of specialty pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is used by us, our contract manufacturing organizations or our other service providers. In addition, we cannot be certain that patents issued to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us.

Furthermore, patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned by us were the first to conceive of the inventions covered by such patents and patent applications or that such inventors were the first to file patent applications for such inventions.

We also may rely on unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with current employees, consultants, collaborators and others. We also have invention or patent assignment agreements with our current employees and certain consultants. There can be no assurance, however, that binding agreements will not be breached, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors. In addition, there can be no assurance that inventions relevant to us will not be developed by a person not bound by an invention assignment agreement with us.

#### Our product development program may not be successful.

In addition to the development of Impracor, we expect to pursue development of potential products in pain management and other therapeutic areas. In particular, we are currently considering potential new product candidates in the muscle relaxant and neuropathic pain fields. We also expect to utilize our relationship with PCCA to identify development opportunities where we perceive an unmet need for a new drug product, and thereby facilitate our future selection, formulation and development of potential product candidates. In addition, our product development program has included cosmetic products, which utilizes the basis of our patented transdermal delivery system technology, Accudel. Since our primary focus will remain seeking FDA approval for Impracor, we currently expect to use limited resources on our other development programs.



None of our potential pharmaceutical product candidates have commenced any clinical trials and there are a number of FDA requirements that we must satisfy in order to commence clinical trials. These requirements will require substantial time, effort and financial resources. We may never satisfy these requirements. In addition, prior to commencing any trials of a drug candidate, we must evaluate whether a market exists for the drug candidate. This is costly and time consuming, and any market studies we rely on may not be accurate. We may expend significant capital and other resources on a drug candidate and find that no commercial market exists for the drug. Further, our relationship with PCCA, on which we intend to rely to facilitate our evaluation of the potential market for future products we may develop, is terminable if we fail to commence efforts to research and develop future products within certain time periods, as set forth in the PCCA License Agreement. We may not be able to meet such requirements within the required time periods or at all, and our relationship with PCCA could be terminated. If we do commence clinical trials of our other potential product candidates, we will still be subject to a number of federal and state regulations, including regulation by the FDA and the Federal Trade Commission on any marketing claims we make, and we may be unable to satisfy these requirements. Any cosmeceutical products we develop may cause undesirable side effects that could limit their use, require their removal from the market and subject us to adverse regulatory action and product liability claims. As a result, we may never successfully develop and obtain approval to market and sell any of our potential product candidates. Even if we do evelop man the is used of our order develop and obtain approval to market and sell any of our potential product candidates. Even if we do evelop may be unable to compete against the many products and treatments currently being offered or under development by other established

#### If approved, failure to comply with continuing federal and state regulations could result in the loss of approvals to market our drugs.

Following initial regulatory approval of any drugs we may develop, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any postmarketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often requires FDA approval before the product, as modified, can be marketed. In addition, we and our contract manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we or our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- · close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

Regulatory review also covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use. Sales and marketing programs are under scrutiny for compliance with various mandated requirements, such as illegal promotions to health care professionals. We are also required to submit information on our open and completed clinical trials to public registries and databases. Failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, be forced to remove a product from the market or experience other adverse consequences, including delay, which would materially harm our financial results. We may not be able to obtain the labeling claims necessary or desirable for product promotion.

# If approved, there is no guarantee that the market will accept our products. If we are not successful in introducing our products or if the market does not accept our products, our business, financial position and results of operations may be materially adversely affected and the market price for our common stock would decline.

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products or if the market for our products is as large as we anticipate. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline.

#### We may be subject to product liability claims.

The development, manufacture, and sale of pharmaceutical and cosmetic products expose us to the risk of significant losses resulting from product liability claims. Although we have obtained and intend to maintain product liability insurance to offset some of this risk, we may be unable to maintain such insurance or it may not cover certain potential claims against us.

In the future, we may not be able to afford to obtain insurance due to rising costs in insurance premiums in recent years. Currently we have been able to secure insurance coverage; however, we may be faced with a successful claim against us in excess of our product liability coverage that could result in a material adverse impact on our business. If insurance coverage is too expensive or is unavailable to us in the future, we may be forced to self-insure against product-related claims. Without insurance coverage, a successful claim against us and any defense costs incurred in defending ourselves may have a material adverse impact on our operations.

#### We may not be successful in receiving additional patents based on our intellectual property strategy.

We have undertaken an effort to examine our intellectual property assets and have or shall file certain patents in certain jurisdictions, with the goal of attaining additional protections for our technologies and any related future products. The applications we have filed or we expect to file may never yield patents that protect our inventions and intellectual property assets. Failure to obtain additional patents may limit our protection against generic drug manufacturers and other parties who may seek to copy or otherwise produce products substantially similar to ours using technologies that may be substantially similar to those we own.

#### The use of our technologies could potentially conflict with the rights of others.

The manufacture, use or sale of our proprietary products may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming and may divert management's attention and our resources. We may not have sufficient resources to bring these actions to a successful conclusion. In such case, we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with patent rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any legal action and a required license under the patent may not available on acceptable terms, if at all.

# We will be dependent on outside manufacturers in the event that we successfully develop our product candidates into commercial products; therefore, we will have limited control of the manufacturing process, access to raw materials, timing for delivery of finished products and costs. One manufacturer may constitute the sole source of one or more of our products.

We expect that third party manufacturers will manufacture all of our products, in the event that we successfully develop our product candidates into commercial products. Currently, certain of our contract manufacturers constitute the sole source of one or more of our products. If any of our existing or future manufacturers cease to manufacture or are otherwise unable to deliver any of our products or any of the components of our products, we may need to engage additional manufacturing partners. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may disrupt or delay our ability to supply our products and reduce our revenues.

Because all of our products, in the event that we successfully develop our product candidates into commercial products, will be manufactured by third parties, we have a limited ability to control the manufacturing process, access to raw materials, the timing for delivery of finished products or costs related to this process. There can be no assurance that our contract manufacturers will be able to produce finished products in quantities that are sufficient to meet demand or at all, in a timely manner, which could result in decreased revenues and loss of market share. There may be delays in the manufacturing process over which we will have no control, including shortages of raw materials, labor disputes, backlog or failure to meet FDA standards. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our financial condition. We are reliant on our third-party manufacturers to maintain their manufacturing facilities in compliance with FDA and other federal, state and/or local regulations including health, safety and environmental standards. If they fail to maintain compliance with FDA or other critical regulations, they could be ordered to curtail operations, which would have a material adverse impact on our business, results of operations and financial condition.

We also rely on our outside manufacturers to assist us in the preparation of key documents such as drug master files and other relevant documents that are required by the FDA as part of the drug approval process and post-approval oversight. Failure by our outside manufacturers to properly prepare and retain these documents could cause delays in obtaining FDA approval of our drug candidates.

### We are dependent on third parties to conduct clinical trials and non-clinical studies of our drug candidates and to provide services for certain core aspects of our business. Any interruption or failure by these third parties to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, results of operations and financial condition.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We expect to engage consultants, advisors, CROs and others to design, conduct, analyze and interpret the results of studies in connection with the research and development of our product candidates. As a result, many important aspects of our product candidates' development are outside our direct control. Such third parties may not perform all of their obligations under arrangements with us or may not perform those obligations satisfactorily.

The CROs with whom we expect to contract for execution of our clinical studies will play a significant role in the conduct of our anticipated clinical studies or assist with our analysis of completed studies and to develop corresponding regulatory strategies. Individuals working at the CROs with whom we expect to contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If these CROs fail to devote sufficient time and resources to our studies, or if their performance is substandard, it would delay the approval of our applications to regulatory agencies and the introduction of our products. Failure of these CROs to meet their obligations could adversely affect development of our product candidates and as a result could have a material adverse effect on our business, financial condition and results of operations. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position.

# We currently have no internal sales and marketing resources and may have to rely on third parties in the event that we successfully commercialize our product.

In order to market any of our products in the United States or elsewhere, we must develop internally or obtain access to sales and marketing forces with technical expertise and with supporting distribution capability in the relevant geographic territory. We may not be able to enter into marketing and distribution arrangements or find a corporate partner to market our drug candidates, and we currently do not have the resources or expertise to market and distribute our products ourselves. If we are not able to enter into marketing or distribution arrangements or find a corporate partner who can provide support for commercialization of our products, we may not be able to successfully commercialize our products. Moreover, any new marketer or distributor or corporate partner for our specific combinations with whom we choose to contract may not establish adequate sales and distribution capabilities or gain market acceptance for our products.

#### If we are unable to retain our key personnel or attract additional professional staff, we may be unable to maintain or expand our business.

As we described elsewhere in this report, we terminated all of our employees following our filing of the Chapter 11 Case. Since the dismissal of the Chapter 11 Case in December 2011, we have focused on rebuilding our management team and engaging consultants in order to begin operating our business. However, because of this history, we may have significant difficulty attracting and retaining necessary employees. In addition, because of the specialized scientific nature of our business, our ability to develop products and to compete will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of, or the failure to recruit, key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions, we may not succeed in retaining personnel or their services under existing agreements or otherwise. There is intense competition for qualified personnel in the pharmaceutical industry, and we may be unable to continue to attract and retain the qualified personnel necessary for the development of our business.



#### **Risks Relating to Our Industry**

# If we are unable to compete with other companies that develop rival products to our products, then we may never gain market share or achieve profitability.

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully, our business, results of operations and financial condition could be adversely affected. Our competitors include brand name and generic manufacturers of pharmaceuticals specializing in transdermal drug delivery, especially those doing business in the United States. In the market for pain management products, our competitors include manufacturers of over-the-counter and prescription pain relievers. Because we are smaller than many of our national competitors, we may lack the financial and other resources needed to compete for market share in the pain management sector. Our other potential drug candidates will also face intense competition from larger and better established pharmaceutical and biotechnology companies. Many of these competitive factors in the pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. If our products are unable to compete with the products of our competitors, we may never gain market share or achieve profitability.

## We may not be able to keep up with the rapid technological change in the biotechnology and pharmaceutical industries, which could make our products obsolete and reduce our potential revenues.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. It is possible that developments by our competitors will render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in developing those products, which may require that we raise additional funds to continue our operations.

#### Our ability to generate revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement from third-party payors.

If we succeed in bringing a specific product to market, we cannot be certain that the products will be considered cost effective and that reimbursement from insurance companies and other third-party payors will be available or, if available, will be sufficient to allow us to sell the products on a competitive basis.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, the market acceptance of these products may be reduced.

#### Changes in the healthcare industry that are beyond our control may be detrimental to our business.

The healthcare industry is changing rapidly as consumers, governments, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling the increase in healthcare costs. In 2009 and 2010, the U.S. Congress adopted legislation regarding health insurance, which has been signed into law. As a result of this new legislation, substantial changes could be made to the current system of paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children's Health Insurance Program, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals, medical devices, or our product candidates and could put pressure on the prices of pharmaceutical products, which could adversely affect our business or products.

### **Risks Relating to our Common Stock**

### You may experience dilution as a result of equity or convertible debt offerings we may effect in the future.

Since inception we have funded our operations primarily through equity and debt financings and we expect to continue to do so in the future. Any future equity or convertible debt offerings we may effect will dilute your ownership interest in the Company. To the extent any of the warrants and options we have issued are ultimately exercised, you will sustain future dilution. We may also acquire or license other technologies or finance strategic alliances by issuing equity, as we did in connection with our recent stock issuance and licensing arrangement with PCCA, which may result in additional dilution to our stockholders.

#### Sales of common stock by our stockholders, or the perception that such sales may occur, could depress our stock price.

Sales of our common stock in the public market could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all.

In addition, the market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, our existing stockholders. We have completed a number of private placements of our common stock and other securities over the last year. Future sales of common stock by significant stockholders, including those who acquired their shares in private placements or who are affiliates, or the perception that such sales may occur, could depress the price of our common stock.

#### An active trading market for shares of our common stock may not develop or be sustained.

Trading in our common stock, which is traded in the over-the-counter market, is sporadic and volatile. We cannot predict the extent to which an active public market for our common stock will develop or be sustained. We have filed an application for the listing of our common stock on The NASDAQ Capital Market. However, approval of our application is contingent upon a number of factors and events, including without limitation whether our proposed public offering is consummated and, if so, the final terms of that offering. Accordingly, our common stock continues to trade on the over-the-counter-market. Even if our common stock begins to trade on The NASDAQ Capital Market in the future, we may not be able to meet the requirements for continued listing going forward. Our common stock has historically been sporadically or "thinly-traded," and as a consequence there may be extended periods when trading activity in our shares is minimal, as compared to a seasoned issuer with a large and steady volume of trading activity. As a result of this lack of liquidity, the trading of relatively small quantities of shares may disproportionately influence the price of those shares in either direction. The market for our common store shares is also characterized by significant price volatility compared to seasoned issuers, and we expect that such volatility will continue. It is possible that a broader or more active public trading market for our common stock will not develop or be sustained.

## Because of their significant stock ownership, some of our existing stockholders will be able to exert control over us and our significant corporate decisions, and sales by management and the Board of Directors from time to time could have an adverse effect on our stock price.

Our executive officers and directors own or have the right to acquire within 60 days, in the aggregate, approximately 23% of the shares of common stock outstanding following such issuance to them. In addition, four individual stockholders hold an additional approximately 45% of our common stock. The sale of even a portion of these shares will likely have a material adverse effect on our stock price. In addition, these persons, acting together, have the ability to exercise significant influence over the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any significant transaction involving us, as well as control our management and affairs. Since our stock ownership is concentrated among a limited number of holders and our Amended and Restated Certificate of Incorporation and Bylaws permit our stockholders to act by written consent, a limited number of stockholders may approve stockholder actions without holding a meeting of stockholders and could control the outcome of actions requiring stockholder approval. This concentration of ownership may harm the market price of our common stock by, among other things:

- delaying, deferring, or preventing a change in control of our company;
- impeding a merger, consolidation, takeover, or other business combination involving our company;
- causing us to enter into transactions or agreements that are not in the best interests of all stockholders; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.



# We have identified material weaknesses in our internal control over financial reporting. If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

As described in our periodic reports filed with the SEC, including Item 4 of Item I of this Quarterly Report on Form 10-Q for the period ended September 30, 2012 and our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, we have identified material weaknesses in our internal controls and procedures. As a result, we have concluded that our disclosure controls and procedures were not effective as of the end of the period covered by these reports. We have implemented, and continue to implement, actions to address these weaknesses and to enhance the reliability and effectiveness of our internal controls and operations; however, the measures we have taken to date and any future measures may not remediate the material weaknesses discussed in our periodic reports. In addition, we may not be able to maintain adequate controls over our financial processes and reporting in the future. We may discover additional material weaknesses, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our consolidated financial statements. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock. Moreover, we will be required to expend significant resources to design, implement and maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. The costs associated with external consultants, as well as internal resources are significant and difficult to predict. As a result, our business, results of operations, financial condition and cash flows could be adversely affected.

#### Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- changes in the pharmaceutical industry and markets;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- new competitors in our market;
- additions or departures of key personnel;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship with our contract manufacturers or with other third parties (including PCCA) and clinical and non-clinical research organizations;
- · industry or regulatory developments; or
- economic and other external factors.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

## We have the right to issue shares of preferred stock. If we were to issue preferred stock, it is likely to have rights, preferences and privileges superior to those of our common stock.

We are authorized to issue 5,000,000 shares of "blank check" preferred stock, with such rights, preferences and privileges as may be determined from time-to-time by our board of directors. Following the conversion of our Series A Preferred Stock on June 29, 2012, we have no shares of preferred stock issued and outstanding. Our board of directors is empowered, without stockholder approval, to issue preferred stock in one or more series, and to fix for any series the dividend rights, dissolution or liquidation preferences, redemption prices, conversion rights, voting rights, and other rights, preferences and privileges for the preferred stock. We have no immediate plans to issue shares of preferred stock. The issuance of shares of preferred stock, depending on the rights, preferences and privileges attributable to the preferred stock, could adversely reduce the voting rights and powers of the common stock and the portion of our assets allocated for distribution to common stock holders in a liquidation event, and could also result in dilution in the book value per share of our thenoutstanding common stock. The preferred stock could also be utilized, under certain circumstances, as a method for raising additional capital or discouraging, delaying or preventing a change in control of the company.

# We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

### Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

The sale by our stockholders of substantial amounts of our common stock in the public market or upon the expiration of any statutory holding period, under Rule 144, or upon expiration of lock-up periods applicable to outstanding shares, or issued upon the exercise of outstanding options or warrants, could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

### **ITEM 6. EXHIBITS**

Exhibit Number	Description
10.1	License Agreement, dated as of August 30, 2012, by and between Imprimis Pharmaceuticals, Inc. and Professional Compounding Centers of America, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 31, 2012)
10.0	
10.2	Stock Purchase Agreement, dated as of August 30, 2012, by and between Imprimis Pharmaceuticals, Inc. and Professional Compounding Centers of America, Inc. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 31, 2012)
10.3	Amendment to Advisory Agreement, dated July 24, 2012, by and between Imprimis Pharmaceuticals, Inc. and Dr. Robert Kammer (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
10.4	Amended and Restated Employment Agreement, dated July 24, 2012, by and between Imprimis Pharmaceuticals, Inc. and Mark L. Baum, Esq. (incorporated herein by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
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10.5	Stand-alone Restricted Stock Unit Agreement, dated July 18, 2012, granted by Imprimis Pharmaceuticals, Inc. to Mark L. Baum (incorporated herein by reference to Exhibit 10.40 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
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	(incorporated herein by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
<u>31.1</u> *	Certification of Mark L. Baum, Esq., Principal Executive Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
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37 1*	Certification pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Mark L.
<u>32.1</u> *	Baum, Esq., Chief Executive Officer
<u>32.2</u> *	Certification pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Andrew
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101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema
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101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase

\* Filed herewith.

\*\* In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

## SIGNATURES

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

Dated: November 14, 2012

## Imprimis Pharmaceuticals, Inc.

By: /s/ Mark L. Baum

Mark L. Baum, Esq. Chief Executive Officer and Director (Principal Executive Officer)

By: /s/ Andrew R. Boll

Andrew R. Boll. Vice President of Accounting and Public Reporting (Principal Financial and Accounting Officer)

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### CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

### I, Mark L. Baum, Chief Executive Officer of Imprimis Pharmaceuticals, Inc., certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Imprimis Pharmaceuticals, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2012

/s/ Mark L. Baum

Mark L. Baum, Esq. Chief Executive Officer (Principal Executive Officer)

### CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

### I, Andrew R. Boll, Principal Accounting and Financial Officer of Imprimis Pharmaceuticals, Inc., certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Imprimis Pharmaceuticals, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2012

/s/ Andrew R. Boll

Andrew R. Boll Vice-President of Accounting and Public Reporting (Principal Accounting and Financial Officer)

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Mark L. Baum, Chief Executive Officer of Imprimis Pharmaceuticals, Inc. (the "Company"), DOES HEREBY CERTIFY that:

- 1. The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (the "**Report**"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
- 2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement this 14th day of November, 2012.

/s/ Mark L. Baum Mark L. Baum, Esq. Chief Executive Officer (Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Imprimis Pharmaceuticals, Inc. and will be retained by Imprimis Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The undersigned, Andrew R. Boll, Principal Accounting and Financial Officer of Imprimis Pharmaceuticals, Inc. (the "Company"), DOES HEREBY CERTIFY that:

- 1. The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (the "**Report**"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
- 2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement this 14th day of November, 2012.

/s/ Andrew R. Boll

Andrew R. Boll Vice-President of Accounting and Public Reporting (Principal Accounting and Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Imprimis Pharmaceuticals, Inc. and will be retained by Imprimis Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.