PROVECTUS PHARMACEUTICALS INC Form 10-Q August 09, 2011

#### 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 June 30, 2011

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

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

Commission file number 000-09410

**PROVECTUS PHARMACEUTICALS, INC.** 

(Exact name of registrant as specified in its charter)

Nevada

90-0031917

(I.R.S. Employer Identification No.)

to

(State or other jurisdiction of incorporation or

organization)

7327 Oak Ridge Highway, Suite A, Knoxville, Tennessee 37931

(Address of principal executive offices) (Zip Code)

866-594-5999

(Registrant s telephone number, including area code)

N/A

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. b Yes o No Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). o Yes o No

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

Large accelerated filer o Accelerated filer b Non-accelerated filer o Smaller reporting company o (Do not check if a smaller reporting company) Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). o Yes b No

The number of shares outstanding of the registrant is a shell company (as defined in Rule 12b-2 of the Act). o Yes p No 108,659,601. The number of shares outstanding of the issuer s 8% convertible preferred stock, par value \$.001 per share, as of July 18, 2011 was 4,293,332.

#### TABLE OF CONTENTS

PART I FINANCIAL INFORMATION
Item 1. Financial Statements (unaudited)
Condensed Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010
Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2011
and 2010
Condensed Consolidated Statements of Stockholders Equity
Condensed Consolidated Statements of Cash Flow
Notes to Condensed Consolidated Financial Statements
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations
Item 3. Quantitative and Qualitative Disclosures About Market Risk
Item 4. Controls and Procedures
PART II OTHER INFORMATION
Item 1 Legal Proceedings

Item 1. Legal Proceedings	13
Item 1A. Risk Factors	13
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	13
Item 3. Defaults Upon Senior Securities	13
Item 4. [Removed and Reserved.]	13
Item 5. Other Information	13
Item 6. Exhibits	13
SIGNATURES	14
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32</u>	
EX-101 INSTANCE DOCUMENT	
EX-101 SCHEMA DOCUMENT	
EX-101 CALCULATION LINKBASE DOCUMENT	

EX-101 LABELS LINKBASE DOCUMENT

EX-101 PRESENTATION LINKBASE DOCUMENT EX-101 DEFINITION LINKBASE DOCUMENT 

#### PART I FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS PROVECTUS PHARMACEUTICALS, INC.

## (A Development-Stage Company) CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2011 (Unaudited)	December 31, 2010 (Audited)
Assets		
Current Assets		
Cash and cash equivalents Prepaid expenses and other current assets	\$ 14,390,120 93,665	\$ 8,086,200
Total Current Assets	14,483,785	8,086,200
Equipment and furnishings, less accumulated depreciation of \$413,219 and \$409,442	23,690	21,320
Patents, net of amortization of \$5,782,817 and \$5,447,257, respectively	5,932,628	6,268,188
Other assets	27,000	27,000
	\$ 20,467,103	\$ 14,402,708
Liabilities and Stockholders Equity		
Current Liabilities		
Accounts payable trade Accrued compensation and payroll taxes Accrued consulting expense Other accrued expenses	\$ 373,043 168,537 71,000 40,000	\$ 418,477 781,262 110,000 40,000
Total Current Liabilities	652,580	1,349,739
Warrant liability	5,039,950	2,353,396
Total Liabilities	5,692,530	3,703,135
Stockholders Equity	4,218	5,390

Preferred stock; par value \$.001 per share; 25,000,000 shares authorized;		
4,218,332 and 5,389,998 shares issued and outstanding, respectively,		
liquidation preference (in aggregate \$3,227,973 and \$4,122,245,		
respectively)		
Common stock; par value \$.001 per share; 150,000,000 authorized;		
108,659,601 and 91,297,883 shares issued and outstanding, respectively	108,660	91,298
Paid-in capital	110,551,690	96,952,908
Deficit accumulated during the development stage	(95,889,995)	(86,350,023)
Total Stockholders Equity	14,774,573	10,699,573
	\$ 20,467,103	\$ 14,402,708
See accompanying notes to consolidated financial st	tatements.	

1

#### PROVECTUS PHARMACEUTICALS, INC. (A Development-Stage Company) CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

Revenues	Three Months Ended June 30, 2011	Three Months Ended June 30, 2010 (As Restated Note 8)	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010 (As Restated Note 8)	Cumulative Amounts from January 17, 2002 (Inception) Through June 30, 2011
OTC product revenue Medical device revenue	\$	\$	\$	\$	\$ 25,648 14,109
Total revenues					39,757
Cost of sales					15,216
Gross profit					24,541
Operating expenses Research and development General and administrative Amortization	2,007,368 3,203,814 167,780	2,130,349 3,223,699 167,780	3,529,472 5,707,485 335,560	2,923,283 5,131,052 335,560	32,814,970 51,270,486 5,782,817
Total operating loss	(5,378,962)	(5,521,828)	(9,572,517)	(8,389,895)	(89,843,732)
Gain on sale of fixed assets					55,075
Loss on extinguishment of debt					(825,867)
Investment income	213	268	369	318	650,712
Gain on change in fair value of warrant liability	843,271	2,137,746	32,176	1,502,747	2,171,821
Net interest expense					(8,098,004)
Net loss	(4,535,478)	(3,383,814)	(9,539,972)	(6,886,830)	\$ (95,889,995)

Dividends on preferred stock		(64,224)		(2,244,392)		(134,158)	(10,216,635)
Net loss applicable to common shareholders	\$	(4,599,702)	\$	(5,628,206)	\$	(9,674,130)	\$ (17,103,465)
Basic and diluted loss per common share	\$	(0.04)	\$	(0.07)	\$	(0.09)	\$ (0.23)
Weighted average number of common shares outstanding basic and diluted		105,794,099		78,132,005		101,914,292	73,580,080
	See accompanying notes to consolidated financial statements.						

#### PROVECTUS PHARMACEUTICALS, INC. (A Development-Stage Company) CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (Unaudited)

	Preferred Number of	l Stock Par	Common S Number of	Stock Par	Paid in	Accumulated	
Dalamaa at	Shares	Value	Shares	Value	capital	Deficit	Total
Balance, at January 17, 2002		\$		\$	\$	\$ \$	5
Issuance to founding shareholders Sale of stock Issuance of stock to employees Issuance of stock			6,000,000 50,000 510,000	6,000 50 510	(6,000) 24,950 931,490		25,000 932,000
for services Net loss for the period from January 17, 2002 (inception) to April 23, 2002 (date of reverse merger)			120,000	120	359,880	(1,316,198)	360,000 (1,316,198)
Balance, at April 23, 2002		\$	6,680,000	\$ 6,680	\$ 1,310,320	\$ (1,316,198) \$	8 802
Shares issued in reverse merger Issuance of stock			265,763	266	(3,911)		(3,645)
for services Purchase and			1,900,000	1,900	5,142,100		5,144,000
retirement of stock Stock issued for acquisition of Valley			(400,000)	(400)	(47,600)		(48,000)
Pharmaceuticals Exercise of			500,007	500	12,225,820		12,226,320
warrants Warrants issued in connection with convertible			452,919	453	126,587		453 126,587

debt Stock and warrants issued for acquisition of Pure-ific Net loss for the period from April 23, 2002 (date of reverse merger) to December 31,2002	25,000	25	26,975	27,000 (5,749,937) (5,749,937)
Balance, at December 31, 2002	\$ 9,423,689	\$ 9,424	\$ 18,780,291	\$ (7,066,135) \$ 11,723,580
Issuance of stock for services Issuance of	764,000	764	239,036	239,800
warrants for services Stock to be			145,479	145,479
issued for services Employee compensation			281,500	281,500
from stock options Issuance of stock			34,659	34,659
pursuant to Regulation S Beneficial	679,820	680	379,667	380,347
conversion related to convertible debt Net loss for the			601,000	601,000
year ended December 31, 2003				(3,155,313) (3,155,313)
Balance, at December 31, 2003	\$ 10,867,509	\$ 10,868	\$ 20,461,632	\$(10,221,448) \$ 10,251,052
Issuance of stock for services Issuance of warrants for	733,872	734	449,190 495,480	449,923 495,480

services Exercise of warrants Employee compensation		132,608	133	4,867		5,000
from stock options Issuance of stock				15,612		15,612
pursuant to Regulation S Issuance of stock and warrants		2,469,723	2,469	790,668		793,137
pursuant to Regulation D Beneficial conversion		1,930,164	1,930	1,286,930		1,288,861
related to convertible debt Issuance of				360,256		360,256
convertible debt with warrants Repurchase of beneficial				105,250		105,250
conversion feature Net loss for the year ended				(258,345)		(258,345)
December 31, 2004					(4,344,525)	(4,344,525)
Balance, at December 31,	¢	16 122 076	ф. 1 <i>с</i> 124	¢ 00.711.540	ф (14 5 (5 072)), ф	0 161 701
2004	\$	16,133,876	\$ 16,134	\$ 23,711,540	\$(14,565,973) \$	9,161,701
Issuance of stock for services Issuance of stock		226,733	227	152,058		152,285
for interest payable Issuance of		263,721	264	195,767		196,031
warrants for services Issuance of warrants for				1,534,405		1,534,405
contractual obligations Exercise of				985,010		985,010
warrants and stock options		1,571,849	1,572	1,438,223 15,752		1,439,795 15,752

Employee compensation from stock options Issuance of stock and warrants pursuant to				
Regulation D Debt conversion	6,221,257	6,221	6,506,955	6,513,176
to common stock Issuance of	3,405,541	3,405	3,045,957	3,049,362
warrants with convertible debt Beneficial conversion			1,574,900	1,574,900
related to convertible debt Beneficial conversion related to interest			1,633,176	1,633,176
Repurchase of beneficial conversion			39,529	39,529
feature			(144,128)	(144,128)
Net loss for the year ended 2005				(11,763,853) (11,763,853)
Balance, at December 31,				
2005	\$ 27,822,977	\$ 27,823	\$ 40,689,144	\$ (26,329,826) \$ 14,387,141
Issuance of stock for services Issuance of stock for interest	719,246	719	676,024	676,743
payable Issuance of	194,327	195	183,401	183,596
warrants for services Exercise of			370,023	370,023
warrants and stock options Employee compensation from stock	1,245,809	1,246	1,188,570	1,189,816
options Issuance of stock and warrants pursuant to	10,092,495	10,092	1,862,456 4,120,329	1,862,456 4,130,421

Regulation D Debt conversion to common stock Beneficial conversion related to interest expense Net loss for the year ended 2006	2,377,512	2,377	1,573,959 16,447	1,576,336 16,447 (8,870,579) (8,870,579)
Balance, at December 31, 2006	\$ 42,452,366	\$ 42,452	\$ 50,680,353	\$ (35,200,405) \$ 15,522,400
Issuance of stock for services Issuance of stock for interest	150,000	150	298,800	298,950
payable Issuance of	1,141	1	1,257	1,258
warrants for services Exercise of			472,635	472,635
warrants and stock options Employee compensation	3,928,957	3,929	3,981,712	3,985,641
from stock options Issuance of stock and warrants			2,340,619	2,340,619
pursuant to Regulation D	2,376,817	2,377	1,845,761	1,848,138
Debt conversion to common stock Net loss for the	490,000	490	367,010	367,500
year ended 2007				(10,005,631) (10,005,631)
Balance, at December 31, 2007	\$ 49,399,281	\$ 49,399	\$ 59,988,147	\$ (45,206,036) \$ 14,831,510
Issuance of stock for services Issuance of	350,000	350	389,650	390,000
warrants for services Exercise of warrants and	3,267,795	3,268	517,820 2,636,443	517,820 2,639,711

stock options Employee compensation from stock options Net loss for the year ended 2008				1,946,066	1,946,066 (10,269,571) (10,269,571)
Balance, at December 31, 2008 Issuance of stock for services Issuance of	\$	53,017,076 796,012	\$ 53,017 796	\$ 65,478,126 694,204	\$ (55,475,607) \$ 10,055,536 695,000
warrants for services Exercise of				1,064,210	1,064,210
warrants and stock options Employee compensation		3,480,485	3,480	2,520,973	2,524,453
from stock options Issuance of stock and warrants				870,937	870,937
pursuant to Regulation D Net loss for the year ended 2009		10,116,653	10,117	6,508,571	6,518,688 (12,322,314) (12,322,314)
Balance, at December 31, 2009	\$	67 410 226	\$ 67.410	\$ 77 137 021	\$ (67,797,921) \$ 9,406,510
Issuance of stock for services	Ų	776,250	776	855,837	856,613
Issuance of warrants for services Exercise of				1,141,593	1,141,593
warrants and stock options Issuance of common stock		3,491,014	3,491	3,100,189	3,103,680
pursuant to Regulation S Issuance of common stock and warrants pursuant to		559,000 11,168,067	559 11,169	418,691 6,335,820	419,250 6,346,989

Regulation D Issuance of preferred stock pursuant to Regulation D Preferred stock conversions into common stock Employee	13,283,324 (7,893,326)	13,283 (7,893)	7,893,326	7,893	4,204,107	4,217,390	)
compensation from stock					2 7 7 0 6 7 0		
options Net loss for the					3,759,650	3,759,650	
year ended 2010						(18,552,102) (18,552,102	!)
Balance, at							
December 31, 2010	5,389,998	\$ 5,390	91,297,883	\$ 91,298	\$ 96,952,908	\$ (86,350,023) \$ 10,699,573	;
Issuance of stock for services	, ,	. ,	150,000	150	147,100	147,250	
Issuance of warrants for			150,000	100	117,100	117,230	•
services					389,172	389,172	2
Exercise of warrants and stock options			6,485,522	6,485	6,304,724	6,311,209	)
Issuance of common stock and warrants							
pursuant to Regulation D			9,554,532	9,555	6,757,786	6,767,341	l
Preferred stock conversions into			<i>),</i> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	7,555	0,757,700	0,707,341	
common stock Net loss for the	(1,171,666)	(1,172)	1,171,664	1,172			
six months ended June 30, 2011						(9,539,972) (9,539,972	2)
Balance, at							
June 30, 2011	4,218,332	\$ 4,218	108,659,601	\$ 108,660	\$ 110,551,690	\$ (95,889,995) \$ 14,774,573	,
	See a	accompany	ving notes to co	onsolidated f 3	inancial stateme	nts.	
							_

#### PROVECTUS PHARMACEUTICALS, INC. (A Development-Stage Company) CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW (Unaudited)

	Six Months	Six Months Ended June 30, 2010	Cumulative Amounts from January 17, 2002 (Inception) through June 30, 2011	
	Ended June 30,	(As Restated		
	2011	<b>Note 8</b> )		
Cash Flows From Operating Activities				
Net loss	\$ (9,539,972)	\$ (6,886,830)	\$ (95,889,995)	
Adjustments to reconcile net loss to net cash used in				
operating activities		1.600	126.220	
Depreciation	3,777	4,689	436,220	
Amortization of patents	335,560	335,560	5,782,817	
Amortization of original issue discount Amortization of commitment fee			3,845,721	
			310,866	
Amortization of prepaid consultant expense Amortization of deferred loan costs			1,295,226 2,261,584	
Accretion of United States Treasury Bills			(373,295)	
Loss on extinguishment of debt			825,867	
Loss on exercise of warrants			236,146	
Beneficial conversion of convertible interest			55,976	
Convertible interest			389,950	
Compensation through issuance of stock options		254,149	10,845,751	
Compensation through issuance of stock		20 .,1 .,	932,000	
Issuance of stock for services	147,250	508,113	8,411,511	
Issuance of warrants for services	389,172	999,991	4,128,599	
Issuance of warrants for contractual obligations	,		985,010	
Gain on sale of equipment			(55,075)	
Gain on change in fair value of warrant liability	(32,176)	(1,502,747)	(2,171,821)	
Change in assets and liabilities				
Prepaid expenses and other current assets	(93,665)	(218,044)	(93,665)	
Accounts payable	(45,434)	(153,379)	369,398	
Accrued expenses	(651,725)	108,922	429,167	
Net cash used in operating activities	(9,487,213)	(6,549,576)	(57,042,042)	
Cash Flows From Investing Activities			100 075	
Proceeds from sale of fixed assets Capital expenditures	(6.147)		180,075	
Proceeds from sales of investments	(6,147)		(74,035)	
Proceeds from sales of investments Purchases of investments			37,010,481	
r urchases of investments			(36,637,186)	
			. –	

Net cash (used in) provided by investing activities	(6,147)		479,335
Cash Flows From Financing Activities			
Net proceeds from loans from stockholder			174,000
Proceeds from convertible debt			6,706,795
Net proceeds from sales of preferred stock and			
warrants		8,908,131	8,908,131
Net proceeds from sales of common stock and			
warrants	9,486,071	5,194,589	37,750,079
Proceeds from exercises of warrants and stock options	6,311,209	1,718,150	20,765,912
Cash paid to retire convertible debt			(2,385,959)
Cash paid for deferred loan costs			(747,612)
Premium paid on extinguishments of debt			(170,519)
Purchase and retirement of common stock			(48,000)
Net cash provided by financing activities	15,797,280	15,820,870	70,952,827
1	- , ,	- , , - · -	· · · · · · · · · · ·
	4		

#### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

	Six Months	Six Months Ended June 30, 2010	Cumulative Amounts from January 17, 2002 (Inception)	
	Ended June 30, 2011	(As Restated Note 8)	through June 30, 2011	
Net change in cash and cash equivalents	\$ 6,303,920	\$ 9,271,294	\$ 14,390,120	
Cash and cash equivalents, at beginning of period	\$ 8,086,200	\$ 3,237,178	\$	
Cash and cash equivalents, at end of period	\$ 14,390,120	\$ 12,508,472	\$ 14,390,120	

Supplemental Disclosure of Noncash Investing and Financing Activities:

During the six months ended June 30, 2011 the Company has reclassified \$485,467 from warrant liability to equity due to exercise of warrants.

See accompanying notes to consolidated financial statements.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

#### 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information pursuant to Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ended December 31, 2011. The Company has evaluated subsequent events through the date the financial statements were issued.

#### 2. Recapitalization and Merger

Provectus Pharmaceuticals, Inc., formerly known as Provectus Pharmaceutical, Inc. and SPM Group, Inc., was incorporated under Colorado law on May 1, 1978. SPM Group ceased operations in 1991, and became a development-stage company effective January 1, 1992, with the new corporate purpose of seeking out acquisitions of properties, businesses, or merger candidates, without limitation as to the nature of the business operations or geographic location of the acquisition candidate.

On April 1, 2002, SPM Group changed its name to Provectus Pharmaceutical, Inc. and reincorporated in Nevada in preparation for a transaction with Provectus Pharmaceuticals, Inc., a privately-held Tennessee corporation (PPI). On April 23, 2002, an Agreement and Plan of Reorganization between Provectus Pharmaceutical and PPI was approved by the written consent of a majority of the outstanding shares of Provectus Pharmaceutical. As a result, Provectus Pharmaceuticals, Inc. issued 6,680,000 shares of common stock in exchange for all of the issued and outstanding shares of PPI. As part of the acquisition, Provectus Pharmaceutical changed its name to Provectus Pharmaceuticals, Inc. and PPI became a wholly-owned subsidiary of Provectus. This transaction was recorded as a recapitalization of PPI.

On November 19, 2002, the Company acquired Valley Pharmaceuticals, Inc., a privately-held Tennessee corporation formerly known as Photogen, Inc., by merging PPI with and into Valley and naming the surviving corporation

Xantech Pharmaceuticals, Inc. Photogen, Inc. was separated from Photogen Technologies, Inc. in a non-pro-rata split-off to some of its shareholders. The assets of Photogen, Inc. consisted primarily of the equipment and intangibles related to its therapeutic activity and were recorded at their fair value. The majority shareholders of Valley were also the majority shareholders of Provectus. Valley had no revenues prior to the transaction with the Company. By acquiring Valley, the Company acquired its intellectual property, including issued U.S. patents and patentable inventions.

#### 3. Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share is computed based on the weighted average number of common shares outstanding. Loss per share excludes the impact of outstanding options and warrants and convertible preferred stock as they are antidilutive. Potential common shares excluded from the calculation at June 30, 2011 and 2010, respectively, relate to 24,348,302 and 28,170,564 from warrants, 11,290,956 and 8,715,955 from options, and 4,218,332 and 13,283,324 from convertible preferred shares. Included in the weighted average number of shares outstanding are 223,214 and 473,567 common shares committed to be issued but not outstanding at June 30, 2011 and 2010, respectively.

#### 4. Equity Transactions

(a) During the three months ended March 31, 2011, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$67,000. During the three months ended June 30, 2011, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$80,250.

(b) During the three months ended March 31, 2011, the Company issued 641,500 warrants to consultants in exchange for services. Consulting costs charged to operations were \$389,172. During the three months ended March 31, 2011, 1,497,328 warrants were exercised for \$1,400,001 resulting in 1,497,328 common shares being issued. 2,048,671

warrants were exercised in December 2010 and the corresponding cash of \$1,915,509 was received in January 2011 and common shares of 2,048,671 were issued in January 2011. During the three months ended March 31, 2011, 193,333 warrants were forfeited. During the three months ended June 30, 2011, 2,322,857 warrants were exercised for \$2,171,801 resulting in 2,322,857 common shares being issued.

(c) In January 2011, we directed Lincoln Park Capital Fund, LLC to purchase 50,000 shares of our common stock for an aggregate purchase price of \$44,665. The Company issued 2,233 common shares to Lincoln Park at a fair market value of \$1,995 as commitment shares in consideration for Lincoln Park to enter into the purchase agreement. In addition to the foregoing investment, under the purchase agreement, we may, in our sole discretion, direct Lincoln Park to purchase up to an additional \$29,950,000 of our common stock over the 30-month term of the purchase agreement at no less than \$0.75 per share. However, under a securities purchase agreement that we entered into in January 2011, we have agreed not to draw down on the Lincoln Park purchase agreement until on or after November 16, 2011. On January 13, 2011, the Company and certain investors entered into a securities purchase agreement, pursuant to which the Company agreed to sell in a registered direct public offering an aggregate of 5,454,550 shares of its common stock and warrants to purchase a total of 7,527,279 shares of its common stock to such investors for aggregate gross proceeds of \$5,100,004. The warrants consist of the following: Series A Warrants to purchase up to 40% of the shares of common stock, Series B Warrants to purchase up to 70% of the shares of common stock, and Series C Warrants to purchase up to 28% of the common stock. The Series A Warrants and the Series C Warrants have an exercise price of \$1.12 per share, subject to adjustment, and expire five years after their issuance. The Series B Warrants have an exercise price \$0.935 per share, subject to adjustment, and expire 150 days after their issuance. The Series C Warrants are only exercisable to the extent that the Series B Warrants are exercised and only in the same percentage that the Series B Warrants are exercised. At March 31, 2011, 1,497,328 of the Series B Warrants were exercised resulting in 598,931 of the Series C Warrants becoming exercisable. The Series A Warrants and Series C Warrants contain additional anti-dilution provisions such that, subject to customary exceptions, in the event of an issuance or deemed issuance by the Company of common stock or securities convertible into common stock at a price per share less than the then applicable exercise price, the then applicable exercise price will be reduced to the new issuance price. The Company determined that these warrants should be classified as liabilities in accordance with Financial Accounting Standards Board Accounting Standards Codification 815-40-15-5 ( ASC 815 ), Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock, because the

warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The value of the warrant liability was determined based on the Monte-Carlo Simulation model at the date the warrants were issued. The Series B Warrants do not contain exercise reset provisions. However, the Series B Warrants required the Company to deliver registered shares of common stock and if the Company was not in a position to do so when the shares are exercised, it is assumed they would have to settle the shares in cash. As a result, the Series B Warrants were recorded as a liability in accordance with ASC 815 and recorded at fair value on the date of issuance using a Black-Scholes option pricing model. The warrant liability initially recorded on January 13, 2011 for all three series of warrants was \$3,204,197. During the three months ended March 31, 2011, 1,497,328 of the Series B Warrants were exercised. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability for this amount, resulting in a gain of \$188,509. The adjusted fair value of the Series B Warrants exercised of \$211,569 was reclassified into additional paid-in capital. At March 31, 2011, the warrant liability for the remaining warrants was revalued resulting in a loss on change in fair value of warrant liability of \$10,306. During the three months ended June 30, 2011, the remainder of the Series B Warrants were exercised which was a total of 2,320,857. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability for this amount, resulting in a gain of \$272,077. The adjusted fair value of the Series B Warrants exercised of \$273,898 was reclassified into additional paid-in capital. At June 30, 2011, the warrant liability for the remaining warrants was revalued resulting in a gain on change in fair value of warrant liability of \$138,995. On April 20, 2011, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$4,615,300. The Company accepted subscriptions, in the aggregate, for 4,120,803 shares of common stock, one year warrants to purchase 2,060,402 shares of common stock, and five year warrants to purchase 2,060,402 shares of common stock. Investors received one year warrants and five year warrants, in each case, to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants was \$1.12. 223,214 of the 4,120,803 common shares sold were committed to be issued but not outstanding at June 30, 2011.

These shares were subsequently issued in July 2011. The Company intends to use the proceeds, after deducting offering expenses estimated to be \$25,000, for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company issued five year warrants to purchase 649,518 shares of common stock with an exercise price of \$1.12 to Network 1 Financial Securities, Inc., which represents 20% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

(d) The Company determined that the warrants issued in March and April, 2010 with the 8% convertible preferred stock should be classified as liabilities in accordance with ASC 815 because the warrants in question contain exercise price reset features that require the exercise price of the warrants be adjusted if the Company issues certain other equity related instruments at a lower price per share. The value of the warrant liability was determined based on the Monte-Carlo Simulation model at the date the warrants were issued. The warrant liability is then revalued at each subsequent quarter end, including at March 31, 2011. At March 31, 2011 there was a loss recognized from the revaluation of the warrant liability of \$989,298. At June 30, 2011 there was a gain recognized from the revaluation of the warrant liability of \$432,199.

Dividends on the 8% Convertible Preferred Stock accrue at an annual rate of 8% of the original issue price and are payable in either cash or common stock. If the dividend is paid in common stock, the number of shares of common stock will equal the quotient of the amount of cash dividends divided by the market price of the stock on the dividend payment date. The dividends are payable quarterly on the 15<sup>th</sup> day after the quarter-end. The Company anticipates paying the dividends in common stock. The Company has a deficit and, as a result, the dividends are recorded against additional paid-in capital. In January 2011, the Company issued 82,169 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of January 15, 2011. At March 31, 2011, the Company recognized dividends of \$69,934 which are included in dividends on preferred stock on the consolidated statement of operations. During the three months ended March 31, 2011 there were 500,001 shares of the Company s redeemable preferred stock that converted into 499,999 shares of the Company s common stock. In April 2011, the Company issued 67,991 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of April 15, 2011. At June 30, 2011, the Company recognized dividends of \$64,224 which are included in dividends on preferred stock on the consolidated statement of operations. During the three months ended June 30, 2011 there were 671,665 shares of the Company s redeemable preferred stock that converted into 671,665 shares of the Company s common stock. In July 2011, the Company issued 63,043 shares of common stock in dividends on preferred stock in lieu of cash dividends due as of July 15, 2011.

#### 5. Stock-Based Compensation

One employee of the Company exercised 133,333 options at an exercise price of \$0.75 per share of common stock for \$100,000 during the three months ended March 31, 2011. One employee of the Company exercised 350,000 options at an exercise price of \$1.00 per share of common stock for \$350,000 during the three months ended June 30, 2011. Another employee of the Company exercised 133,333 options at an exercise price of \$0.75 per share of common stock for \$100,000 during the three months ended June 30, 2011. There were no options issued for the three and six months ended June 30, 2011 and no stock-based compensation expense recognized for the three and six months ended June 30, 2011 and 2010.

#### 6. Related Party Transaction

The Company paid one non-employee member of the board \$90,000 for consulting services performed as of June 30, 2011. The Company paid another non-employee member of the board \$12,000 for consulting services performed as of June 30, 2011.

7

#### 7. Fair Value of Financial Instruments

The FASB s authoritative guidance on fair value measurements establishes a framework for measuring fair value, and expands disclosure about fair value measurements. This guidance enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. Under this guidance, assets and liabilities carried at fair value must be classified and disclosed in one of the following three categories:

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

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

In determining the appropriate levels, the Company performs a detailed analysis of the assets and liabilities that are measured and reported on a fair value basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs are classified as Level 3. The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. The warrant liability is a derivative instrument and is classified as Level 3. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants except for the Series B Warrants. Significant assumptions used at March 31, 2011 for the 2010 warrants include a weighted average term of 4.0 years, a 5% probability that the warrant exercise price would be reset, volatility of 70.7% and a risk free interest rate of 2.24%. Significant assumptions used at June 30, 2011 for the 2010 warrants include a weighted average term of 3.7 years, a 5% probability that the warrant exercise price would be reset, volatility of 67.7% and a risk free interest rate of 1.29%. Significant assumptions used at March 31, 2011 for the 2011 warrants include a weighted average term of 4.8 years, a 5% probability that the warrant exercise price would be reset, a volatility range between 70.65% and 70.67% and a risk free interest rate range between 1.99% and 2.24%. Significant assumptions used at June 30, 2011 for the 2011 warrants include a weighted average term of 4.5 years, a 5% probability that the warrant exercise price would be reset, a volatility of 67.7% and a risk free interest rate of 1.76%. For the Series B Warrants the Black-Scholes method was used to estimate the fair value of the warrants resulting in a warrant liability of \$757,542 at March 31, 2011. There was no warrant liability for the Series B Warrants at June 30, 2011 because they had all been exercised at June 30, 2011.

The warrant liability measured at fair value on a recurring basis is as follows:

	Total	Level 1	Level 2	Level 3
Derivative instruments:				
Warrant liability at June 30, 2011	\$5,039,950	\$	\$	\$5,039,950
Warrant liability at December 31, 2010	\$2,353,396	\$	\$	\$2,353,396
	. 1 . 4 C 1			C

A reconciliation of the warranty liability measured at fair value on a recurring basis with the use of significant unobservable inputs (Level 3) from January 1, 2011 to June 30, 2011 follows:

8. Restatement Restatement of June 30, 2010	
Balance at June 30, 2011	\$ 5,039,950
Issuance of warrants Net gain included in earnings Exercise of warrants	3,204,197 (32,176) (485,467)
Balance at January 1, 2011	\$ 2,353,396

The Company issued warrants to purchase 5,291,654 shares of the Company s common stock in March 2010 and warrants to purchase 1,350,000 shares of the Company s common stock in April 2010 (collectively, the Warrants ). The Warrants have an exercise price of \$1.00 per share and expire five years after their issuance. The Warrants contain certain anti-dilution provisions pursuant to which future issuances or deemed issuances of warrants, in certain circumstances as defined in the agreement, without consideration or for consideration per share less than the applicable exercise price in effect immediately prior to such issue, will result in the exercise price of the Warrants being reduced to the consideration per share received by the Company for such deemed issue. The Company originally classified the Warrants as equity in its 2010 quarterly filings.

8

#### Table of Contents

The Company has determined that the Warrants should be classified as liabilities in accordance with ASC 815 due to the anti-dilution provisions contained in the Warrants. The Company reflected the necessary adjustment in the fourth quarter of 2010 and calculated the impact on its quarterly reports on Form 10-Q for the quarterly periods ending March 31, June 30, and September 30, 2010. The applicable line items on the Form 10-Q Consolidated Statements of Operations have been restated below for the three and six month periods ending June 30, 2010.

The Company determined its quantitative valuation of the Warrants using a Monte-Carlo Simulation model. Management of the Company believes that the Monte-Carlo Simulation model is appropriate because it is a dynamic model, which accommodates variable inputs.

The impact of the application of ASC 815 on the affected line items of the Company s quarterly financial statement is set forth below:

#### \* \* \* \* \*

#### **Consolidated Statement of Operations** for the Three Months Ended June 30, 2010

	As Previously			
	Reported	Adjustments	As Restated	
Total operating loss	\$ (5,521,828)	\$	\$(5,521,828)	
Gain on change in fair value of warrant liability		2,137,746	2,137,746	
Net loss	(5,521,560)	2,137,746	(3,383,814)	
Dividends on preferred stock	(2,590,033)	345,641	(2,244,392)	
Net loss applicable to common shareholders	(8,111,593)	2,483,387	(5,628,206)	
Basic and diluted loss per common share	(0.10)		(0.07)	

#### Consolidated Statement of Operations for the Six Months Ended June 30, 2010

	As Previously		
	Reported	Adjustments	As Restated
Total operating loss	\$ (8,389,895)	\$	\$ (8,389,895)
Gain on change in fair value of warrant liability		1,502,747	1,502,747
Net loss	(8,389,577)	1,502,747	(6,886,830)
Dividends on preferred stock	(10,947,617)	730,982	(10,216,635)
Net loss applicable to common shareholders	(19,337,194)	2,233,729	(17,103,465)
Basic and diluted loss per common share	(0.26)		(0.23)
	9		

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

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the accompanying unaudited financial statements, our Annual Report on Form 10-K/A for the year ended December 31, 2010, which includes additional information about our critical accounting policies and practices and risk factors, and Item 1A of Part II of this report, which updates those risk factors. Historical results and percentage relationships set forth in the statement of operations, including trends which might appear, are not necessarily indicative of future operations.

#### **Plan of Operation**

We have implemented our integrated business plan, including execution of the current and next phases in clinical development of our pharmaceutical products and continued execution of research programs for new research initiatives.

We intend to proceed as rapidly as possible with a licensure of our dermatology drug product candidate (PH-10) on the basis of our Phase 2 atopic dermatitis and psoriasis results, which are in process of being further developed. We intend to also proceed as rapidly as possible with a majority stake asset sale and subsequent licensure of our OTC products that can be sold with a minimum of regulatory compliance and with the further development of revenue sources through a majority stake asset sale and subsequent licensing of our existing medical device, imaging, and biotech intellectual property portfolio. Although we believe that there is a reasonable basis for our expectation that we will become profitable due to both the licensure of PH-10 and the asset sale of a majority stake via a spin-out transaction of the wholly-owned subsidiaries that contain the non-core assets and subsequent licensure of our non-core products, we cannot assure you that we will be able to achieve, or maintain, a level of profitability sufficient to meet our operating expenses.

Our current plans include continuing to operate with our four employees during the immediate future, but we have added two additional consultants to the two we already had, and anticipate adding additional personnel if necessary in the next 12 months. Our current plans also include minimal purchases of new property, plant and equipment, and increased research and development for additional clinical trials.

We believe that our prescription drug candidates PV-10 and PH-10 provide us with two products in multiple indications, which have been shown in clinical trials to be safe to treat serious cancers and diseases of the skin. We continue to develop clinical trials for these products to show their safety and efficacy, which we believe will be shown based on data in previous studies. Together with our OTC products, medical device, biotech and other non-core technologies, which we intend to sell or license in the future, we believe this combination represents the foundation for maximizing shareholder value this year and next.

#### **Results of Operations**

#### Comparison of Three and Six Months Ended June 30, 2011 and June 30, 2010 Revenues

We had no revenue during the three and six months ended June 30, 2011 and 2010.

#### Research and Development

Research and development costs of \$2,007,368 for the three months ended June 30, 2011 included payroll of \$1,224,777, consulting and contract labor of \$684,230, legal of \$34,111, insurance of \$12,500, lab supplies and pharmaceutical preparations of \$29,979, rent and utilities of \$19,862, and depreciation expense of \$1,909. Research and development costs of \$2,130,349 for the three months ended June 30, 2010 included payroll of \$1,749,395, consulting and contract labor of \$232,640, legal of \$58,347, insurance of \$12,500, lab supplies and pharmaceutical preparations of \$59,268, rent and utilities of \$16,116, and depreciation expense of \$2,083. The decrease in payroll is the result of a decrease in bonuses and no stock-based compensation expense. The increase in consulting and contract labor is due primarily to the completion of both the Liver Phase 1 study as well as the completion of enrollment for the Psoriasis Phase 2C study.

Research and development costs of \$3,529,472 for the six months ended June 30, 2011 included payroll of \$2,154,524, consulting and contract labor of \$1,216,111, legal of \$56,507, insurance of \$29,247, lab supplies and

pharmaceutical preparations of \$33,864, rent and utilities of \$35,442, and depreciation expense of \$3,777. Research and development costs of \$2,923,283 for the six months ended June 30, 2010 included payroll of \$2,328,835, consulting and contract labor of \$323,250, legal of \$91,156, insurance of \$25,000, lab supplies and pharmaceutical preparations of \$117,500, rent and utilities of \$32,853, and depreciation expense of \$4,689. The decrease in payroll is the result of no stock-based compensation expense. The increase of approximately \$800,000 in consulting and contract labor is primarily the result of an increase in manufacturing preparation, characterization and specifications for PV-10 and PH-10, as well as an increase in intellectual property related consulting expense. Additionally, there was an increase in consulting and contract labor due to the completion of both the Liver Phase 1 study as well as the completion of enrollment for the Psoriasis Phase 2C study.

#### General and Administrative

General and administrative expenses decreased by \$19,885 in the three months ended June 30, 2011 to \$3,203,814 from \$3,223,699 for the three months ended June 30, 2010.

General and administrative expenses increased by \$576,433 in the six months ended June 30, 2011 to \$5,707,485 from \$5,131,052 for the six months ended June 30, 2010. The increase resulted primarily from additional investor relations and conference expenses.

10

#### Investment Income

Investment income was insignificant in both the three and six months ended June 30, 2011 and 2010.

#### Liquidity and Capital Resources

Our cash and cash equivalents were \$14,390,120 at June 30, 2011, compared with \$8,086,200 at December 31, 2010. The increase of approximately \$6,300,000 was due primarily to proceeds from the sale of common stock as well as the exercise of warrants and stock options.

At our current cash expenditure rate, we believe our cash and cash equivalents on hand at June 30, 2011 will be sufficient to meet our current and planned operating needs until well into 2013 without consideration being given to additional cash inflows that might occur from the exercise of existing warrants or future sales of equity securities. We are seeking to improve our cash flow through both the licensure of PH-10 on the basis of our Phase 2 atopic dermatitis and psoriasis results, and the majority stake asset sale and licensure of our OTC products as well as other non-core assets. However, we cannot assure you that we will be successful in either licensing PH-10 or selling a majority stake of the OTC and other non-core assets via a spin-out transaction and licensing our existing non-core products. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our long-term requirements in 2013 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placements, the exercise of existing warrants outstanding, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to shareholders.

#### **Critical Accounting Policies**

Management s discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. Management bases its estimates on historical experience and assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe there have been no material changes to the items that we disclosed as our critical accounting policies under Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, in our 2010 Form 10-K/A.

New Accounting Pronouncements

None.

#### Contractual Obligations Leases

We lease office and laboratory space in Knoxville, Tennessee, on an annual basis, renewable for one year at our option. We have no lease commitments as of June 30, 2011. We are currently leasing on a month-to-month basis. **Forward-Looking Statements** 

## This Quarterly Report on Form 10-Q contains forward-looking statements as defined under U.S. federal securities

laws. These statements reflect management s current knowledge, assumptions, beliefs, estimates,