

PROVECTUS BIOPHARMACEUTICALS, INC.

Form 10-Q

May 08, 2014

[Table of Contents](#)

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended March 31, 2014**

.. **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 000-09410**

**PROVECTUS BIOPHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**



**Table of Contents**

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

<u>Cautionary Note Regarding Forward-Looking Statements</u>	1
<u>Item 1. Financial Statements (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets</u>	2
<u>Condensed Consolidated Statements of Operations</u>	3
<u>Condensed Consolidated Statements of Stockholders' Equity</u>	4
<u>Condensed Consolidated Statements of Cash Flow</u>	8
<u>Notes to Condensed Consolidated Financial Statements</u>	9
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	15
<u>Item 4. Controls and Procedures</u>	15

**PART II OTHER INFORMATION**

<u>Item 1. Legal Proceedings</u>	16
<u>Item 1A. Risk Factors</u>	16
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	17
<u>Item 3. Defaults Upon Senior Securities</u>	17
<u>Item 4. Mine Safety Disclosures</u>	17
<u>Item 5. Other Information</u>	17
<u>Item 6. Exhibits</u>	18
<b><u>SIGNATURES</u></b>	19

**Table of Contents**

**CAUTIONARY NOTE REGARDING 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, and expectations and express management's current views of future performance, results, and trends and may be identified by their use of terms such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will, or similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligation to update such statements after this date.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013, and elsewhere in this Quarterly Report on Form 10-Q), and the following:

our ability to license our dermatology drug product candidate, PH-10, on the basis of our Phase 2 atopic dermatitis and psoriasis results, which are in the process of being further developed in conjunction with mechanism of action studies;

our determination, based on guidance from the FDA, whether to proceed with or without a partner with a Phase 3 trial of PV-10 to treat locally advanced cutaneous melanoma and the costs associated with such a trial if it is necessary, and whether or not we obtain Breakthrough Therapy Designation;

our determination whether to license PV-10, our melanoma drug product candidate, and other solid tumors such as liver cancer, if such licensure is appropriate considering the timing and structure of such a license, or to commercialize PV-10 on our own to treat melanoma and other solid tumors such as liver cancer; and

our ability to raise additional capital if we determine to commercialize PH-10 and/or PV-10 on our own, although our expectation is to be acquired by a prospective pharmaceutical or biotech concern prior to commercialization.

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****PROVECTUS BIOPHARMACEUTICALS, INC.**

(A Development-Stage Company)

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>March 31, 2014</b> <b>(Unaudited)</b>	<b>December 31,</b> <b>2013</b> <b>(Audited)</b>
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 16,648,916	\$ 15,696,243
Total Current Assets	16,648,916	15,696,243
Equipment and furnishings, less accumulated depreciation of \$431,047 and \$429,331, respectively	28,397	30,113
Patents, net of amortization of \$7,628,397 and \$7,460,617, respectively	4,087,048	4,254,828
Other assets	27,000	27,000
Total Assets	\$ 20,791,361	\$ 20,008,184
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable - trade	\$ 725,288	\$ 348,869
Accrued consulting expense	61,282	61,282
Other accrued expenses	48,584	102,795
Total Current Liabilities	835,154	512,946
<b>Long-Term Liability</b>		
Warrant liability	5,436,056	12,866,572
Total Liabilities	6,271,210	13,379,518
<b>Stockholders' Equity</b>		
Preferred stock; par value \$.001 per share; 25,000,000 shares authorized; Series A 8% convertible preferred stock, 0 and 33,334 shares issued and outstanding, respectively, liquidation preference \$0.75 (for 2013 in aggregate \$25,001)		33
Common stock; par value \$.001 per share; 250,000,000 authorized; 173,125,972 and 159,751,724 shares issued and outstanding, respectively	173,126	159,752
Paid-in capital	167,065,112	152,519,701

Edgar Filing: PROVECTUS BIOPHARMACEUTICALS, INC. - Form 10-Q

Deficit accumulated during the development stage	(152,718,087)	(146,050,820)
Total Stockholders Equity	14,520,151	6,628,666
Total Liabilities and Stockholders Equity	\$ 20,791,361	\$ 20,008,184

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

## PROTECTUS BIOPHARMACEUTICALS, INC.

(A Development-Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Cumulative Amounts from January 17, 2002 (Inception) Through March 31, 2014
Revenues			
OTC product revenue	\$	\$	\$ 25,648
Medical device revenue			14,109
Total revenues			39,757
Cost of sales			15,216
Gross profit			24,541
Operating expenses			
Research and development	1,157,883	740,516	47,852,291
General and administrative	3,055,944	2,338,403	78,003,097
Amortization	167,780	167,780	7,628,397
Total operating loss	(4,381,607)	(3,246,699)	(133,459,244)
Gain on sale of fixed assets			55,075
Loss on extinguishment of debt			(825,867)
Investment income	1,373	27	655,915
Loss on change in fair value of warrant liability	(2,287,033)	(923,510)	(11,045,962)
Net interest expense			(8,098,004)
Net loss	(6,667,267)	(4,170,182)	\$ (152,718,087)
Dividends on preferred stock		(1,076,934)	(12,026,710)
Net loss applicable to common shareholders	\$ (6,667,267)	\$ (5,247,116)	\$ (164,744,797)
Basic and diluted loss per common share	\$ (0.04)	\$ (0.04)	
Weighted average number of common shares outstanding basic and diluted	168,859,658	120,702,172	

See accompanying notes to condensed consolidated financial statements.





Table of Contents

## PROTECTUS BIOPHARMACEUTICALS, INC.

(A Development-Stage Company)

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

	Preferred Stock	Common Stock		Paid in capital	Accumulated Deficit	Total	
	Number of Shares	Par Value	Number of Shares	Par Value			
<b>Balance, at January 17, 2002</b>	\$			\$	\$	\$	
Issuance to founding shareholders			6,000,000	6,000	(6,000)		
Sale of stock			50,000	50	24,950	25,000	
Issuance of stock to employees			510,000	510	931,490	932,000	
Issuance of stock for services			120,000	120	359,880	360,000	
Net loss for the period from January 17, 2002 (inception) to April 23, 2002 (date of reverse merger)					(1,316,198)	(1,316,198)	
<b>Balance, at April 23, 2002</b>	\$		6,680,000	\$ 6,680	\$ 1,310,320	\$ (1,316,198)	\$ 802
Shares issued in reverse merger			265,763	266	(3,911)	(3,645)	
Issuance of stock for services			1,900,000	1,900	5,142,100	5,144,000	
Purchase and retirement of stock			(400,000)	(400)	(47,600)	(48,000)	
Stock issued for acquisition of Valley Pharmaceuticals			500,007	500	12,225,820	12,226,320	
Exercise of warrants			452,919	453		453	
Warrants issued in connection with convertible debt					126,587	126,587	
Stock and warrants issued for acquisition of Pure-ific			25,000	25	26,975	27,000	
Net loss for the period from April 23, 2002 (date of reverse merger) to December 31, 2002					(5,749,937)	(5,749,937)	

<b>Balance, at December 31, 2002</b>	\$	9,423,689	\$ 9,424	\$ 18,780,291	\$ (7,066,135)	\$ 11,723,580
Issuance of stock for services		764,000	764	239,036		239,800
Issuance of warrants for services				145,479		145,479
Stock to be issued for services				281,500		281,500
Employee compensation from stock options				34,659		34,659
Issuance of stock pursuant to Regulation S		679,820	680	379,667		380,347
Beneficial conversion related to convertible debt				601,000		601,000
Net loss for the year ended December 31, 2003					(3,155,313)	(3,155,313)

<b>Balance, at December 31, 2003</b>	\$	10,867,509	\$ 10,868	\$ 20,461,632	\$ (10,221,448)	\$ 10,251,052
Issuance of stock for services		733,872	734	449,190		449,923
Issuance of warrants for services				495,480		495,480
Exercise of warrants		132,608	133	4,867		5,000
Employee compensation from stock options				15,612		15,612
Issuance of stock pursuant to Regulation S		2,469,723	2,469	790,668		793,137
Issuance of stock and warrants pursuant to Regulation D		1,930,164	1,930	1,286,930		1,288,861
Beneficial conversion related to convertible debt				360,256		360,256
Issuance of convertible debt with warrants				105,250		105,250
Repurchase of beneficial conversion feature				(258,345)		(258,345)
Net loss for the year ended December 31, 2004					(4,344,525)	(4,344,525)

**Table of Contents**

	Preferred Stock Number of Shares	Par Value	Common Stock Number of Shares	Par Value	Paid in capital	Accumulated Deficit	Total
<b>Balance, at December 31, 2004</b>		\$	16,133,876	\$ 16,134	\$ 23,711,540	\$ (14,565,973)	\$ 9,161,701
Issuance of stock for services			226,733	227	152,058		152,285
Issuance of stock for interest payable			263,721	264	195,767		196,031
Issuance of warrants for services					1,534,405		1,534,405
Issuance of warrants for contractual obligations					985,010		985,010
Exercise of warrants and stock options			1,571,849	1,572	1,438,223		1,439,795
Employee compensation from stock options					15,752		15,752
Issuance of stock and warrants pursuant to Regulation D			6,221,257	6,221	6,506,955		6,513,176
Debt conversion to common stock			3,405,541	3,405	3,045,957		3,049,362
Issuance of warrants with convertible debt					1,574,900		1,574,900
Beneficial conversion related to convertible debt					1,633,176		1,633,176
Beneficial conversion related to interest expense					39,529		39,529
Repurchase of beneficial conversion feature					(144,128)		(144,128)
Net loss for the year ended 2005						(11,763,853)	(11,763,853)

**Table of Contents**

<b>Balance, at December 31, 2005</b>	\$	27,822,977	\$ 27,823	\$ 40,689,144	\$ (26,329,826)	\$ 14,387,141
Issuance of stock for services		719,246	719	676,024		676,743
Issuance of stock for interest payable		194,327	195	183,401		183,596
Issuance of warrants for services				370,023		370,023
Exercise of warrants and stock options		1,245,809	1,246	1,188,570		1,189,816
Employee compensation from stock options				1,862,456		1,862,456
Issuance of stock and warrants pursuant to Regulation D		10,092,495	10,092	4,120,329		4,130,421
Debt conversion to common stock		2,377,512	2,377	1,573,959		1,576,336
Beneficial conversion related to interest expense				16,447		16,447
Net loss for the year ended 2006					(8,870,579)	(8,870,579)
<b>Balance, at December 31, 2006</b>	\$	42,452,366	\$ 42,452	\$ 50,680,353	\$ (35,200,405)	\$ 15,522,400
Issuance of stock for services		150,000	150	298,800		298,950
Issuance of stock for interest payable		1,141	1	1,257		1,258
Issuance of warrants for services				472,635		472,635
Exercise of warrants and stock options		3,928,957	3,929	3,981,712		3,985,641
Employee compensation from stock options				2,340,619		2,340,619
Issuance of stock and warrants pursuant to Regulation D		2,376,817	2,377	1,845,761		1,848,138

Debt conversion to common stock		490,000	490	367,010		367,500
Net loss for the year ended 2007					(10,005,631)	(10,005,631)
<b>Balance, at December 31, 2007</b>	\$	49,399,281	\$ 49,399	\$ 59,988,147	\$ (45,206,036)	\$ 14,831,510
Issuance of stock for services		350,000	350	389,650		390,000
Issuance of warrants for services				517,820		517,820
Exercise of warrants and stock options		3,267,795	3,268	2,636,443		2,639,711
Employee compensation from stock options				1,946,066		1,946,066
Net loss for the year ended 2008					(10,269,571)	(10,269,571)
<b>Balance, at December 31, 2008</b>	\$	53,017,076	\$ 53,017	\$ 65,478,126	\$ (55,475,607)	\$ 10,055,536
Issuance of stock for services		796,012	796	694,204		695,000
Issuance of warrants for services				1,064,210		1,064,210
Exercise of warrants and stock options		3,480,485	3,480	2,520,973		2,524,453
Employee compensation from stock options				870,937		870,937
Issuance of stock and warrants pursuant to Regulation D		10,116,653	10,117	6,508,571		6,518,688
Net loss for the year ended 2009					(12,322,314)	(12,322,314)
<b>Balance, at December 31, 2009</b>	\$	67,410,226	\$ 67,410	\$ 77,137,021	\$ (67,797,921)	\$ 9,406,510
Issuance of stock for services		776,250	776	855,837		856,613
Issuance of warrants for services				1,141,593		1,141,593

Exercise of warrants and stock options			3,491,014	3,491	3,100,189		3,103,680
Issuance of common stock pursuant to Regulation S			559,000	559	418,691		419,250
Issuance of common stock and warrants pursuant to Regulation D			11,168,067	11,169	6,335,820		6,346,989
Issuance of preferred stock pursuant to Regulation D	13,283,324	13,283			4,204,107		4,217,390
Preferred stock conversions into common stock	(7,893,326)	(7,893)	7,893,326	7,893			
Employee compensation from stock options					3,759,650		3,759,650
Net loss for the year ended 2010						(18,552,102)	(18,552,102)

**Table of Contents**

<b>Balance, at December 31, 2010</b>	5,389,998	\$ 5,390	91,297,883	\$ 91,298	\$ 96,952,908	\$ (86,350,023)	\$ 10,699,573
Issuance of stock for services			350,000	350	332,400		332,750
Issuance of warrants for services					945,116		945,116
Exercise of warrants and stock options			7,185,522	7,185	6,616,126		6,623,311
Issuance of common stock and warrants pursuant to Regulation D			9,905,062	9,905	7,031,334		7,041,239
Sale of non-controlling interest in Pure-ific Corporation and warrants					443,500		443,500
Preferred stock conversions into common stock	(1,858,333)	(1,859)	1,858,331	1,859			
Employee compensation from stock options					3,368,950		3,368,950
Net loss for the year ended 2011						(19,434,699)	(19,434,699)
<b>Balance, at December 31, 2011</b>	3,531,665	\$ 3,531	110,596,798	\$ 110,597	\$ 115,690,334	\$ (105,784,722)	\$ 10,019,740
Issuance of stock for services			550,000	550	455,950		456,500
Issuance of warrants for services					1,512,026		1,512,026
Issuance of common stock and warrants pursuant to			6,227,647	6,228	4,784,316		4,790,544

<b>Regulation D</b>							
Preferred stock conversions into common stock	(1,053,480)	(1,053)	1,053,480	1,053			
Employee compensation from stock options					183,028		183,028
Net loss for the year ended 2012						(12,568,354)	(12,568,354)
<b>Balance, at December 31, 2012</b>							
	2,478,185	\$ 2,478	118,427,925	\$ 118,428	\$ 122,625,654	\$ (118,353,076)	\$ 4,393,484
Issuance of stock for services			750,000	750	525,250		526,000
Issuance of warrants for services					1,786,824		1,786,824
Exercise of warrants and stock options			6,319,594	6,320	7,829,150		7,835,470
Issuance of common stock and warrants pursuant to Regulation D			28,409,353	28,409	18,390,926		18,419,335
Issuance of preferred stock and warrants pursuant to Regulation D	3,400,001	3,400			1,248,650		1,252,050
Preferred stock conversions into common stock	(5,844,852)	(5,845)	5,844,852	5,845			
Dividends on preferred stock					(29,063)		(29,063)
Employee compensation from stock options					142,310		142,310
Net loss for the year ended 2013						(27,697,744)	(27,697,744)
<b>Balance, at December 31,</b>							
	33,334	\$ 33	159,751,724	\$ 159,752	\$ 152,519,701	\$ (146,050,820)	\$ 6,628,666



<b>2013</b>						
Issuance of stock for services			75,000	75	137,425	137,500
Issuance of warrants for services					900,317	900,317
Exercise of warrants and stock options			13,265,914	13,266	13,507,669	13,520,935
Preferred stock conversions into common stock	(33,334)	(33)	33,334	33		
Net loss for the three months ended March 31, 2014					(6,667,267)	(6,667,267)
<b>Balance, at March 31, 2014</b>	\$		173,125,972	\$ 173,126	\$ 167,065,112	\$ (152,718,087) \$ 14,520,151

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

## PROVECTUS BIOPHARMACEUTICALS, INC.

(A Development-Stage Company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Unaudited)

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Cumulative Amounts from January 17, 2002 (Inception) through March 31, 2014
<b>Cash Flows From Operating Activities</b>			
Net loss	\$ (6,667,267)	\$ (4,170,182)	\$ (152,718,087)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	1,716	1,550	454,048
Amortization of patents	167,780	167,780	7,628,397
Amortization of original issue discount			3,845,721
Amortization of commitment fee			310,866
Amortization of prepaid consultant expense			1,295,226
Amortization of deferred loan costs			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			14,540,039
Compensation through issuance of stock			932,000
Issuance of stock for services	137,500	48,750	9,717,011
Issuance of warrants for services	900,317	409,640	8,883,710
Issuance of warrants for contractual obligations			985,010
Gain on sale of equipment			(55,075)
Loss on change in fair value of warrant liability	2,287,033	923,510	11,045,962
Change in assets and liabilities			
Prepaid expenses and other current assets		(140,784)	
Accounts payable	376,419	(193,544)	721,643
Accrued expenses	(54,211)	(23,140)	259,496
Net cash used in operating activities	(2,850,713)	(2,976,420)	(88,757,805)
<b>Cash Flows From Investing Activities</b>			
Proceeds from sale of fixed assets			180,075
Capital expenditures			(96,570)
Proceeds from sales of investments			37,010,481

Purchases of investments				(36,637,186)
Net cash provided by investing activities				456,800
<b>Cash Flows From Financing Activities</b>				
Net proceeds from loans from stockholder				174,000
Proceeds from convertible debt				6,706,795
Net proceeds from sales of preferred stock and warrants		2,550,000		11,458,131
Net proceeds from sales of common stock and warrants		3,522,869		61,233,856
Proceeds from exercises of warrants and stock options	3,803,386			28,314,792
Cash paid for preferred dividends				(29,063)
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)
Net proceeds from sale of non-controlling interest in Pure-ific Corporation				443,500
Purchase and retirement of common stock				(48,000)
Net cash provided by financing activities	3,803,386	6,072,869		104,949,921
Net change in cash and cash equivalents	\$ 952,673	\$ 3,096,449	\$	16,648,916
Cash and cash equivalents, at beginning of period	15,696,243	1,221,701		
Cash and cash equivalents, at end of period	\$ 16,648,916	\$ 4,318,150	\$	16,648,916

**Supplemental Disclosure of Noncash Investing and Financing Activities:**

During the three months ended March 31, 2014, the Company has reclassified \$9,717,549 from warrant liability to equity due to the exercise of a portion of our warrants.

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

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 three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ended December 31, 2014. The Company has evaluated subsequent events through the date the condensed consolidated financial statements were issued.

**2. Recapitalization, Merger, Reincorporation and Name Change**

Provectus Biopharmaceuticals, Inc., formerly known as Provectus Pharmaceuticals, Inc., 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.

On December 16, 2013, Provectus Pharmaceuticals, Inc. was reincorporated in Delaware and changed its name to Provectus Biopharmaceuticals, Inc.

**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 March 31, 2014 and 2013, respectively, relate to 58,090,500 and 43,169,822 from warrants, 13,893,334 and 15,140,956 from options, and 0 and 5,285,186 from convertible preferred shares.

#### **4. Equity Transactions**

(a) During the three months ended March 31, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$137,500. During the three months ended March 31, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$48,750.

(b) During the three months ended March 31, 2014, the Company issued 733,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$900,317. During the three months ended March 31, 2014, 121,500 warrants were forfeited. During the three months ended March 31, 2014, 12,522,198 warrants were exercised on a cashless basis resulting in 9,100,824 common shares being issued. During the three months ended March 31, 2014, 3,036,218 warrants were exercised for

**Table of Contents**

\$2,672,364 resulting in 3,036,218 common shares issued. The warrant exercises include the exercises of warrants classified as liabilities that are described below in (c), (d) and (e). During the three months ended March 31, 2013, the Company issued 1,924,973 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$409,640. During the three months ended March 31, 2013, 859,833 warrants were forfeited.

As the fair market value of these services was not readily determinable, these services were valued based on the fair market value of the warrants, determined using the Black-Scholes option-pricing model.

(c) The Company determined that warrants issued January 13, 2011 and referred to as Series A Warrants and Series C Warrants 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 or upon exercise. For the three months ended March 31, 2014 and 2013, there was a total loss recognized from the revaluation of the warrant liability of \$1,153,835 and \$311,062, respectively. During the three months ended March 31, 2014, 858,825 of the Series A Warrants were exercised. During the three months ended March 31, 2014, 697,092 of the Series C Warrants were exercised. The Company determined the fair value of the Series A and Series C Warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the Series A and Series C Warrants exercised of \$3,911,370 was reclassified into additional paid-in capital.

(d) In March and April 2010, the Company had an issuance of 8% Convertible Preferred Stock with warrants. The Company determined that warrants issued 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 or upon exercise. For the three months ended March 31, 2014 and 2013, there was a total loss recognized from the revaluation of the warrant liability of \$211,422 and \$446,698, respectively. During the three months ended March 31, 2014, 1,756,665 of the warrants included in the warrant liability were exercised. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the warrants exercised of \$2,096,013 was reclassified into additional paid-in capital.

(e) In February 2013, the Company had an issuance of Series A 8% Convertible Preferred Stock with warrants. The Company determined that warrants issued with the Series A 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 preferred stock was determined to have characteristics more akin to equity than debt. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be bifurcated and classified as a liability. The proceeds received from the issuance of the preferred stock were first allocated to the fair value of the warrants with the remainder allocated to the preferred stock. The fair value of the preferred stock if converted on the date of issuance was greater than the value allocated to the preferred stock. As a result, a beneficial conversion amount was recorded upon issuance. The fair value of the warrants recorded from the February 2013 issuance was \$1,297,950 resulting in a beneficial conversion amount of \$1,025,950. The beneficial conversion has been recorded as a deemed dividend as of March 31, 2013 and is included in dividends on preferred stock on the consolidated statements of operations. 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 or upon exercise. For the three months ended March 31, 2014 and 2013, there was a total loss

recognized from the revaluation of the warrant liability of \$921,776 and \$165,750, respectively. During the three months ended March 31, 2014, 1,650,000 of the warrants included in the warrant liability were exercised. The Company determined the fair value of the warrants exercised on the date of exercise and adjusted the related warrant liability accordingly. The adjusted fair value of the warrants exercised of \$3,710,166 was reclassified into additional paid-in capital.

Dividends on the Series A 8% Convertible Preferred Stock accrued at an annual rate of 8% of the original issue price and were payable in either cash or common stock. If the dividend was paid in common stock, the number of shares of common stock equaled the quotient of the amount of cash dividends divided by the market price of the stock on the dividend payment date. The dividends were payable quarterly on the 15th day after the quarter-end. The Company paid the dividends in common stock although was required to pay the initial dividends due in cash. The Company had a deficit and, as a result, the dividends were recorded against additional paid-in capital. At March 31, 2013, the Company recognized dividends of \$29,063 which are included in dividends on preferred stock on the consolidated statement of operations and were paid in April 2013. At March 31, 2014, the Company recognized no dividends because of the full conversion of preferred stock to common stock as of January 15, 2014.

In January 2014, there were 33,334 shares of the Company's Series A 8% Convertible Preferred Stock that converted into 33,334 shares of the Company's common stock. At January 15, 2014, there were no shares of Series A 8% Convertible Preferred Stock outstanding.

**Table of Contents**

**5. Stock-Based Compensation**

One employee of the Company exercised 25,000 options at an exercise price of \$0.95 per share of common stock for \$23,750, 14,248 options at an exercise price of \$0.75 per share of common stock for \$10,686 and 600,000 options at an exercise price of \$0.93 per share of common stock for \$558,000 during the three months ended March 31, 2014. Another employee of the Company exercised 300,000 options at an exercise price of \$1.10 per share of common stock for \$330,000 during the three months ended March 31, 2014. Another employee of the Company exercised 189,624 options at an exercise price of \$1.10 per share of common stock for \$208,586 during the three months ended March 31, 2014. One employee of the Company forfeited 300,000 stock options on February 26, 2014.

**6. Related Party Transaction**

The Company paid one non-employee member of the board \$6,000 for the expanded access protocol oversight performed as of March 31, 2014.

**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 certain of the Company's financial instruments, including cash and cash equivalents and accounts payable, approximates the carrying value due to the relatively short maturity of such instruments. 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. Significant assumptions used at March 31, 2014 for the 2010 warrants include a weighted average term of 0.9 years, a 5% probability that the warrant exercise price would be reset, volatility range of 66.5% to 129.7% and a risk free interest rate of 0.13%. Significant assumptions used at March 31, 2014 for the 2011 warrants include a weighted average term of 1.8 years, a 5% probability that the warrant exercise price would be reset, volatility of 101.8% and a risk free interest rate of 0.29%. Significant assumptions used at March 31, 2014 for the 2013 warrants include a weighted average term of 3.9 years, a 5% probability that the warrant exercise price would be reset, volatility of 84.7% and a risk free interest rate range of 0.77% to 1.32%.

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



	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Derivative instruments:</b>				
Warrant liability at March 31, 2014	\$ 5,436,056	\$	\$	\$ 5,436,056
Warrant liability at December 31, 2013	\$ 12,866,572	\$	\$	\$ 12,866,572

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, 2014 to March 31, 2014 is as follows:

Balance at January 1, 2014	\$ 12,866,572
Issuance of warrants	
Change in fair value of warrants included in earnings	2,287,033
Exercise of warrants	(9,717,549)
Balance at March 31, 2014	\$ 5,436,056

**Table of Contents**

**8. Subsequent Events**

The Company has evaluated subsequent events through the date of the filing of these financial statements. In April 2014, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$4,342,250. The Company accepted subscriptions, in the aggregate, for 1,736,900 shares of common stock and five year warrants to purchase 1,736,900 shares of common stock. Investors received five year fully vested warrants to purchase up to 100% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$3.00 per share. The purchase price for each share of common stock together with the warrants was \$2.50. The Company plans to use the proceeds 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 paid \$564,493 and issued five year fully vested warrants to purchase 260,535 shares of common stock with an exercise price of \$2.50 to Network 1 Financial Securities, Inc., which represents 15% of the total number of shares of common stock sold to investors solicited by Network 1 Financial Securities, Inc.

On April 30, 2014, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent ( Cantor ), under which the Company may issue and sell shares of its common stock having an aggregate offering proceeds of up to \$50,000,000 from time to time through Cantor, acting as sales agent.

**Table of Contents**

**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 for the year ended December 31, 2013 ( 2013 Form 10-K ), 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.

Our current plans include continuing to operate with our four employees during the immediate future, as well as our four primary consultants and various vendor relationships, 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 as necessary and appropriate.

We believe that our prescription drug candidates PV-10 and PH-10 provide us with two therapeutic products in multiple indications, which have been shown in clinical trials to be safe to treat serious cancers and diseases of the skin, respectively. Also, important immunologic data with PV-10 has been corroborated and characterized by institutions such as Moffitt Cancer Center in Tampa, Florida. We continue to develop clinical trials for these products to show their safety and efficacy, which we believe will continue to be shown based on data in previous studies, and which we believe will result in one or more license transactions with pharmaceutical and/or biotech partners. Together with our 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 beyond.

**Results of Operations**

**Comparison of Three Months Ended March 31, 2014 and March 31, 2013**

*Revenues*

We had no revenue during the three months ended March 31, 2014 and 2013.

*Research and Development*

Research and development costs of \$1,157,883 for the three months ended March 31, 2014 included payroll of \$492,258, consulting and contract labor of \$234,258, legal of \$26,471, insurance of \$54,803, lab supplies and pharmaceutical preparations of \$326,410, rent and utilities of \$21,967, and depreciation expense of \$1,716. Research and development costs of \$740,516 for the three months ended March 31, 2013 included payroll of \$334,155, consulting and contract labor of \$263,970, legal of \$26,564, insurance of \$75,000, lab supplies and pharmaceutical preparations of \$21,355, rent and utilities of \$17,922, and depreciation expense of \$1,550. The increase overall is due primarily to an increase of over \$300,000 in lab supplies and pharmaceutical preparations for new drug substance

manufactured with the recently patented Rose Bengal synthesis in the quarter ended March 31, 2014.

*General and Administrative*

General and administrative expenses increased by \$717,541 in the three months ended March 31, 2014 to \$3,055,944 from \$2,338,403 for the three months ended March 31, 2013. General and administrative expenses were very similar for both periods; however, almost \$600,000 in increased expense is due to the higher stock price during the three months ended March 31, 2014 versus the three months ended March 31, 2013, which resulted in higher noncash expenses as costs to operations from the calculation of both stock and warrants for services.

*Investment Income*

Investment income was insignificant in both the three months ended March 31, 2014 and 2013.

*Loss on change in fair value of warrant liability*

Loss on change in fair value of warrant liability increased by \$1,363,523 in the three months ended March 31, 2014 to \$2,287,033 from \$923,510 for the three months ended March 31, 2013. This activity results from accounting for the warrant liability described in Footnotes 4(c), 4(d) and 4(e) to the financial statements which is primarily attributed to our increase in common stock price.

## Table of Contents

### **Liquidity and Capital Resources**

Our cash and cash equivalents were \$16,648,916 at March 31, 2014, compared with \$15,696,243 at December 31, 2013. The increase of approximately \$1.0 million was due primarily to \$3.8 million cash received from warrant and stock option exercises in the quarter ended March 31, 2014 offset by \$2.8 million of operating cash expenses.

By managing variable cash expenses due to minimal fixed costs, we believe our cash and cash equivalents on hand at March 31, 2014, in addition to the cash we received subsequent to the quarter ended March 31, 2014, will be sufficient to meet our current and planned operating needs until well into 2015 without consideration being given to additional cash inflows that might occur from the exercise of existing warrants or future sales of equity securities, although we may, in our sole discretion, direct Alpha Capital Anstalt ( Investor ) to purchase up to an additional \$30,000,000 of our common stock per an existing agreement with the Investor. In addition, on April 30, 2014, we entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co., as sales agent ( Cantor ), under which we may issue and sell shares of our common stock having an aggregate offering proceeds of up to \$50,000,000 from time to time through Cantor, acting as sales agent.

Therefore, our ability to continue as a going concern is reasonably assured due to our cash and cash equivalents on hand at March 31, 2014 and with additional cash from warrant and stock option exercises in 2014, and financing described in Footnote 8 to the financial statements. Given our current rate of expenditures and our ability to curtail or defer certain controllable expenditures, we do not need to raise additional capital to further develop PV-10 on our own to treat locally advanced cutaneous melanoma, cancers of the liver, recurrent breast cancer, pancreatic cancer and other indications because we plan to license PH-10 for psoriasis and other related indications described as inflammatory dermatoses, strategically monetize PV-10 through appropriate regional license transactions, and also complete the spin-out of Pure-ific Corporation and the other non-core subsidiaries. Additionally, our existing funds are sufficient to meet minimal necessary expenses until well into 2015. Furthermore, our financial position and corporate governance are such that we meet the relevant listing requirements of both NYSE MKT and NASDAQ. We plan to list on either exchange as appropriate in the near future.

We believe our continued development of PV-10 with existing funds will yield proof-of-concept evidence to support expected best-in-class clinical benefit to treat a wide range of solid tumor indications due to its unique immuno-chemoablation mechanism of action. Likewise, we believe our development of PH-10 with existing funds will yield proof-of-concept evidence to support expected best-in-class clinical benefit to treat a wide range of inflammatory dermatoses due to its unique non-steroidal anti-inflammatory mechanism of action.

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 primarily the geographic licensure of PV-10 on the basis of our Phase 2 melanoma and Phase 1 liver results in certain areas of the world, as well as pursuing a strategic investment strategy, including equity sales to potential pharmaceutical and/or biotech partners. In addition, the data now available and forthcoming from Moffitt Cancer Center in Tampa, Florida has been and is expected to be particularly helpful in supporting our development plans with both the FDA and prospective partners. The geographic areas of interest for PV-10 principally include China, India, Japan and Middle East and North Africa (MENA). We are encouraged by the interest in both PV-10 and PH-10 on a geographic basis and are continuing discussions with potential partners.

We are also considering the global licensure of PV-10 as well since it has come to our attention that this is of interest to potential partners. We have provided data on a confidential basis to both potential global and geographic partners for both PV-10 and PH-10 via a secure electronic data room that is monitored 24 hours a day, seven days a week and houses formal data submissions to the FDA as well as various corporate governance related documents.

We also expect to continue with the majority stake asset sale and licensure of our non-core assets. However, the primary objective of the Company is to strategically monetize the core value of PV-10 and PH-10 through various transactions, leveraging value creation up to and including an appropriate merger and acquisition transaction that includes upfront cash and acquirer stock in exchange for Company ownership. Shareholders are also expected to receive for each share of stock a contingency value right (CVR) that is expected to trade on a major exchange. This CVR will facilitate potential upside for shareholders post-acquisition of the Company by enabling cash and stock dividends to flow to the owner of the CVR, which can be reinvested or otherwise sold for cash.

We believe regulatory clarity, including one or more breakthrough therapy designations, is determined by specifying the expected approval pathways of both PV-10 and PH-10. This may include the potential for breakthrough therapy designation for PV-10 to treat locally advanced cutaneous melanoma and an accelerated approval path for PV-10 to treat this indication. Such clarity will help facilitate transactions with potential partners. Additionally, the existing and forthcoming mechanism of action related clinical and nonclinical data for both PV-10 and PH-10 will further aid in both regulatory clarity and transactions with potential partners.

## **Table of Contents**

However, we cannot assure you that we will be successful in either licensing of PH-10 or PV-10, any equity transaction, 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 2015 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placements, the exercise of existing warrants and outstanding stock options, 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 Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our 2013 Form 10-K.

### *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 a lease commitment of \$45,000 as of March 31, 2014.

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

We had no holdings of financial or commodity instruments as of March 31, 2014, other than cash and cash equivalents, short-term deposits, money market funds, and interest bearing investments in U.S. governmental debt securities. We have accounted for certain warrants issued in March and April 2010, January 2011 and February 2013 as liabilities at their fair value upon issuance, which are remeasured at each period end with the change in fair value recorded in the statement of operations. See notes 4 and 7 of the interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

All of our business is transacted in U.S. dollars and, accordingly, foreign exchange rate fluctuations have not had a significant impact on us, and they are not expected to have a significant impact on us in the foreseeable future.

## **ITEM 4. CONTROLS AND PROCEDURES.**

(a) Evaluation of Disclosure Controls and Procedures. Our chief executive officer and chief financial officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as that term is defined in Rule 13a-15(e) under the Exchange Act) as of March 31, 2014, the end of the fiscal quarter covered by this

Quarterly Report on Form 10-Q. Based on that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective.

(b) Changes in Internal Controls. There has been no change in our internal control over financial reporting that occurred during the fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



---

**Table of Contents**

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS.**

Except as described below, we are not involved in any legal proceedings nor are we party to any pending claims that we believe could reasonably be expected to have a material adverse effect on our business, financial condition, or results of operations.

On January 2, 2013, Glenn Kleba (the Plaintiff) derivatively on behalf of the Company, filed a shareholder derivative complaint in the Circuit Court for the State of Tennessee, Knox County (the Court), against H. Craig Dees, Timothy C. Scott, Eric A. Wachter, and Peter R. Culpepper (collectively, the Executives), Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, together with the Executives, the Individual Defendants), and against the Company as a nominal defendant (the Shareholder Derivative Lawsuit). The Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on the Plaintiff's allegations that the defendants authorized and/or accepted stock option awards in violation of the terms of the Company's 2002 Stock Plan (the Plan) by issuing stock options in excess of the amounts authorized under the Plan and delegated to defendant H. Craig Dees the sole authority to grant himself and the other Executives cash bonuses that the Plaintiff alleges to be excessive.

In April 2013, the Company's Board of Directors appointed a special litigation committee (the SLC) to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The SLC conducted its investigation, and proceedings in the case were stayed pending the conclusion of the committee's investigation. The Company has established a reserve of \$100,000 for potential liabilities because such is the amount of the self-insured retention of its insurance policy.

On March 6, 2014, the Company filed a Joint Notice of Settlement (the Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Settlement are the Plaintiff and the Individual Defendants. The Settlement was evidenced by a binding term sheet (the Term Sheet) executed by the SLC, the Plaintiffs and all Individual Defendants between February 13 and February 23, 2014. The Term Sheet provided that the settling parties had resolved the derivative claims to their mutual satisfaction. The Individual Defendants did not admit the validity of any claims or allegations and the Plaintiff did not admit that any claims or allegations lack merit or foundation. By the terms of the Term Sheet, (i) the Executives each agreed (A) to re-pay to the Company \$2.24 Million of the cash bonuses they received in 2010 and 2011, which amount equals 70% of such bonuses or an estimate of the after-tax net proceeds to each Executive; provided, however, that subject to certain terms and conditions set forth in the term sheet, which sets forth the terms and conditions of the Settlement (the Term Sheet), the Executives are entitled to a 2:1 credit such that total actual repayment may be \$1.12 Million each; (B) to reimburse the Company for 25% of the actual costs, net of recovery from any other source, incurred by the Company as a result of the Shareholder Derivative Lawsuit; and (C) to grant to the Company a first priority security interest in 1,000,000 shares of the Company's common stock owned by each such Executive to serve as collateral for the amounts due to the Company under the Term Sheet; (ii) Drs. Dees and Scott and Mr. Culpepper agreed to retain incentive stock options for 100,000 shares but shall forfeit 50% of the nonqualified stock options granted to each such Executive in both 2010 and 2011. The Term Sheet also requires that each of the Executives enter into new employment agreements with the Company and that the Company adhere to certain corporate governance principles and processes in the future. Under the Settlement, Messrs. Fuchs and Smith and Dr. McMasters have the option to either (A) pay the Company \$25,000 cash or (B) forfeit options to purchase 50,000 shares of the Company's common stock. The Company, the Plaintiff and the Individual Defendants will release each other from any and all claims related to the Shareholder Derivative Lawsuit, as well as dismiss the Shareholder Derivative Lawsuit with prejudice upon the Company and the Individual Defendants entering into a formal settlement agreement. Formal settlement agreements and related documentation

were contemplated to be prepared and executed as necessary.

On May 4, 2014, signed settlement agreements on behalf of Stuart Fuchs, Kelly M. McMasters and Alfred E. Smith, IV were delivered by their counsel to counsel for the SLC and have been executed by the SLC chairman and approved by counsel for the Plaintiffs. However, final settlement agreements with the Executives have not yet been executed because of the lack of agreement regarding the payment of attorney fees for Plaintiff's counsel. On May 6, 2014, the SLC filed a Notice of Determination that Derivative Lawsuit Should Proceed as to Certain Defendants and Settled as to Others (the Notice of Determination) with the Court in which it is alleged that the Executives repudiated the Settlement evidenced by the Term Sheet and that the Shareholder Derivative Lawsuit should proceed against the Executives. On May 7, 2014, the Executives filed a Notice of Objection (the Objection) in which they deny that they have repudiated the Settlement and assert that they remain committed to complete the Settlement.

The Settlement, both as to Stuart Fuchs, Kelly M. McMasters and Alfred E. Smith, IV, and as to the Executives if presented, remains subject to approval by the Court after such notice as is approved by the Court and such hearing as may be required by the Court. The Court will determine (1) if the terms and conditions of the Settlement are fair, reasonable and adequate and in the best interest of the Company and its shareholders, (2) if the judgment, as provided for in the Settlement, should be entered, and (3) if the request of Plaintiff's counsel for an award of attorneys' fees and reimbursement of expenses should be granted and, if so, in what amount or, if any agreement reached regarding the amount of such fees and expenses should be approved.

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

There have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013 other than the additional disclosure of the risk factor listed below.

## **Table of Contents**

*A breakthrough therapy designation (BTD) by the FDA for our product candidate may not be granted or lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval.*

As reported previously, a Type C meeting was held with the FDA's Division of Oncology Products 2 on December 16, 2013. The purpose of the meeting was to determine which of the available paths that our investigational oncology drug PV-10 could take in pursuit of initial FDA approval and commercialization. As a result of this meeting, we submitted data from our Phase 2 study in a formal BTD request on March 21, 2014.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

The breakthrough therapy designation process is a new and uncertain process, in which the majority of requests for designation have been denied. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that PV-10 meets the criteria for designation as a breakthrough therapy for locally advanced cutaneous melanoma, the FDA may disagree and instead determine not to make such designation. Even if such designation is granted, of which no assurances may be given, the receipt of a BTD for PV-10 may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if PV-10 qualifies as a breakthrough therapy for one or more indications, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, which would deny us the benefits of such designation.

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

During the three months ended March 31, 2014, the Company issued 733,000 warrants to consultants in exchange for services.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 (the Securities Act ) by virtue of Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

The Company intends to use any net proceeds from the exercises of these issuances for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

## **ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

## **ITEM 5. OTHER INFORMATION.**

None.

**Table of Contents**

**ITEM 6. EXHIBITS**

**Exhibit**

<b>No.</b>	<b>Description</b>
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).
32	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 (Section 906 Certification).
101	Interactive Data Files.*

\* The documents formatted in XBRL (Extensible Business Reporting Language) and attached as Exhibit 101 to this report are deemed not filed as part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.

Table of Contents

**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.

PROVECTUS BIOPHARMACEUTICALS, INC.

May 8, 2014

By: /s/ Peter R. Culpepper  
Peter R. Culpepper  
On behalf of the registrant and as Chief Financial  
Officer and Chief Operating Officer (Principal  
Financial Officer)

19

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

<b>No.</b>	<b>Description</b>
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).
32	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 (Section 906 Certification).
101	Interactive Data Files.*

\* The documents formatted in XBRL (Extensible Business Reporting Language) and attached as Exhibit 101 to this report are deemed not filed as part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.