

PROVECTUS BIOPHARMACEUTICALS, INC.

Form 10-Q

August 07, 2014

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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 June 30, 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 001-36457

PROVECTUS BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

90-0031917
(I.R.S. Employer
Identification No.)

7327 Oak Ridge Highway, Suite A,

Knoxville, Tennessee
(Address of principal executive offices)

37931
(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. Yes 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). Yes 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 Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The number of shares outstanding of the registrant's common stock, par value \$.001 per share, as of June 30, 2014 was 176,638,439.

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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, as supplemented by the risk factors disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, and elsewhere in this Quarterly Report on Form 10-Q), and the following:

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;

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;

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; and

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

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(A Development-Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2014 (Unaudited)	December 31, 2013 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 18,126,036	\$ 15,696,243
Total Current Assets	18,126,036	15,696,243
Equipment and furnishings, less accumulated depreciation of \$432,763 and \$429,331, respectively	26,681	30,113
Patents, net of amortization of \$7,796,177 and \$7,460,617, respectively	3,919,268	4,254,828
Other assets	27,000	27,000
	\$ 22,098,985	\$ 20,008,184
Liabilities and Stockholders Equity		
Current Liabilities		
Accounts payable trade	\$ 479,857	\$ 348,869
Accrued consulting expense	104,042	61,282
Other accrued expenses	232,568	102,795
Total Current Liabilities	816,467	512,946
Long-Term Liability		
Warrant liability	1,302,961	12,866,572
Total Liabilities	2,119,428	13,379,518
Stockholders Equity		
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; 300,000,000 authorized; 176,638,439 and 159,751,724 shares issued and outstanding, respectively	176,638	159,752
Paid-in capital	173,164,422	152,519,701

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Deficit accumulated during the development stage	(153,361,503)	(146,050,820)
Total Stockholders Equity	19,979,557	6,628,666
	\$ 22,098,985	\$ 20,008,184

See accompanying notes to condensed consolidated financial statements.

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PROTECTUS BIOPHARMACEUTICALS, INC.

(A Development-Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013	Cumulative Amounts from January 17, 2002 (Inception) Through June 30, 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	1,025,535	778,349	2,183,418	1,518,865	48,877,826
General and administrative	2,966,569	2,340,706	6,022,513	4,679,109	80,969,666
Amortization	167,780	167,780	335,560	335,560	7,796,177
Total operating loss	(4,159,884)	(3,286,835)	(8,541,491)	(6,533,534)	(137,619,128)
Gain on sale of fixed assets					55,075
Loss on extinguishment of debt					(825,867)
Investment income	1,443	256	2,816	283	657,358
(Loss) gain on change in fair value of warrant liability	3,515,025	909,206	1,227,992	(14,304)	(7,530,937)
Net interest expense					(8,098,004)
Net loss	(643,416)	(2,377,373)	(7,310,683)	(6,547,555)	(153,361,503)
Dividends on preferred stock		(73,024)		(1,149,958)	(12,026,710)
Net loss applicable to common shareholders	\$ (643,416)	\$ (2,450,397)	\$ (7,310,683)	\$ (7,697,513)	\$ (165,388,213)
Basic and diluted loss per common share	\$ (0.00)	\$ (0.02)	\$ (0.04)	\$ (0.06)	

Weighted average number of common shares outstanding basic and diluted	175,554,000	127,114,868	172,225,322	123,926,235
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See accompanying notes to condensed consolidated financial statements.

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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		
Balance, at January 17, 2002	\$			\$	\$	\$
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)
Balance, at April 23, 2002	\$		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					(5,749,937)	(5,749,937)

of reverse merger) to
December 31, 2002

Balance, at December 31, 2002	\$	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)

Balance, at December 31, 2003	\$	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

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	Preferred Stock	Common Stock					
	Number of Shares	Number of Shares	Par Value	Par Value	Paid in capital	Accumulated Deficit	Total
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)
Balance, at December 31, 2004	\$	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)

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	Preferred Stock	Common Stock				
	Number of Shares	Number of Shares	Par Value	Paid in capital	Accumulated Deficit	Total
Balance, at December 31, 2005	\$	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)
Balance, at December 31, 2006	\$	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)
	\$	49,399,281	\$ 49,399	\$ 59,988,147	\$ (45,206,036)	\$ 14,831,510

Balance, at December 31, 2007					
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)

Balance, at December 31, 2008	\$	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)

Balance, at December 31, 2009	\$	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

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	Preferred Stock		Common Stock		Paid in capital	Accumulated Deficit	Total
	Number of Shares	Par Value	Number of Shares	Par Value			
Issuance of preferred stock and warrants 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)
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			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)
Balance, at December 31, 2011	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 Regulation D			6,227,647	6,228	4,784,316		4,790,544
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)
Balance, at December 31, 2012	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			28,409,353	28,409	18,390,926		18,419,335

Regulation D										
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)		
Balance, at December 31, 2013	33,334	\$	33	159,751,724	\$	159,752	\$	(146,050,820)	\$	6,628,666
issuance of stock for services				150,000		150		277,600		277,750

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	Preferred Stock		Common Stock		Paid in capital	Accumulated Deficit	Total
	Number of Shares	Par Value	Number of Shares	Par Value			
Issuance of warrants for services					1,350,319		1,350,319
Reclassification of warrant liability					10,335,619		10,335,619
Cash proceeds from exercise of warrants and stock options			14,703,381	14,703	4,333,183		4,347,886
Issuance of common stock and warrants pursuant to Regulation D			2,000,000	2,000	4,348,000		4,350,000
Preferred stock conversions into common stock	(33,334)	(33)	33,334	33			
Net loss for the six months ended June 30, 2014						(7,310,683)	(7,310,683)
Balance, at June 30, 2014		\$	176,638,439	\$ 176,638	\$ 173,164,422	\$ (153,361,503)	\$ 19,979,557

See accompanying notes to condensed consolidated financial statements.

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PROTECTUS BIOPHARMACEUTICALS, INC.

(A Development-Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Unaudited)

	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013	Cumulative Amounts from January 17, 2002 (Inception) through June 30, 2014
Cash Flows From Operating Activities			
Net loss	\$ (7,310,683)	\$ (6,547,555)	\$ (153,361,503)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	3,432	3,100	455,764
Amortization of patents	335,560	335,560	7,796,177
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	277,750	98,250	9,857,261
Issuance of warrants for services	1,350,319	1,341,295	9,333,712
Issuance of warrants for contractual obligations			985,010
Gain on sale of equipment			(55,075)
Loss (gain) on change in fair value of warrant liability	(1,227,992)	14,304	7,530,937
Change in assets and liabilities			
Prepaid expenses and other current assets		(93,034)	
Accounts payable	130,988	(178,673)	476,212
Accrued expenses	172,533	81,437	486,240
Net cash used in operating activities	(6,268,093)	(4,945,316)	(92,175,185)
Cash Flows From Investing Activities			
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
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		2,550,000		11,458,131
Net proceeds from sales of common stock and warrants	4,350,000	5,817,698		65,583,856
Proceeds from exercises of warrants and stock options	4,347,886	21,000		28,859,292
Cash paid for preferred dividends		(29,063)		(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	8,697,886	8,359,635		109,844,421
Net change in cash and cash equivalents	\$ 2,429,793	\$ 3,414,319	\$	18,126,036
Cash and cash equivalents, at beginning of period	15,696,243	1,221,701		
Cash and cash equivalents, at end of period	\$ 18,126,036	\$ 4,636,020	\$	18,126,036

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Supplemental Disclosure of Noncash Investing and Financing Activities:

During the six months ended June 30, 2014, the Company has reclassified \$10,335,619 from warrant liability to equity due to the exercise of a portion of our warrants.

See accompanying notes to condensed consolidated financial statements.

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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, 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 and Merger

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 June 30, 2014 and 2013, respectively, relate to 58,311,418 and 50,358,525 from warrants, 13,718,334 and 15,097,206 from options, and 0 and 4,881,666 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.

During the three months ended June 30, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$140,250. During the three months ended June 30, 2013, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$49,500.

(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

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9,100,824 common shares being issued. During the three months ended March 31, 2014, 3,036,218 warrants were exercised for \$2,672,364 resulting in 3,036,218 common shares issued. 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.

During the three months ended June 30, 2014, the Company issued 202,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$450,002. During the three months ended June 30, 2014, 315,000 warrants were forfeited. During the three months ended June 30, 2014, 1,594,082 warrants were exercised on a cashless basis resulting in 915,467 common shares being issued. During the three months ended June 30, 2014, 372,000 warrants were exercised for \$372,000 resulting in 372,000 common shares issued. During the three months ended June 30, 2013, the Company issued 2,605,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$931,655. During the three months ended June 30, 2013, 1,051,500 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. For the three months ended March 31, 2014 and 2013, there was a 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. For the three months ended June 30, 2014 and 2013, there was a gain recognized from the revaluation of the warrant liability of \$186,262 and \$221,149, respectively. 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 in 2014 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. For the three months ended March 31, 2014 and 2013, there was a 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. For the three months ended June 30, 2014 and 2013, there was a gain recognized from the revaluation of the warrant liability of \$3,285,793 and \$399,057, respectively. During the three months ended June 30, 2014, 133,232 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 in 2014 of \$2,377,133 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. For the three months ended March 31, 2014 and 2013, there was a 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. For the three months ended June 30, 2014 and 2013, there was a gain recognized from the revaluation of the warrant liability of \$42,970 and \$289,000, respectively. During the three months ended June 30, 2014, 200,000 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 in 2014 of \$4,047,116 was reclassified into additional paid-in capital.

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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 June 30, 2013, the Company recognized dividends of \$50,860 which are included in dividends on preferred stock on the consolidated statement of operations. In 2014, the Company recognized no dividends because of the full conversion of preferred stock to common stock as of January 15, 2014.

(f) 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. As of January 15, 2014, there were no shares of Series A 8% Convertible Preferred Stock outstanding.

(g) During the three months ended June 30, 2014 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$5,000,000. The Company accepted subscriptions, in the aggregate, for 2,000,000 shares of common stock and five year warrants to purchase 2,000,000 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 used 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 \$650,000 and issued five year fully vested warrants to purchase 300,000 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.

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.

One employee of the Company exercised 25,000 options at an exercise price of \$0.95 per share of common stock for \$23,750 during the three months ended June 30, 2014. Another employee of the Company exercised 100,000 options at an exercise price of \$1.25 per share of common stock for \$125,000 during the three months ended June 30, 2014. A former non-employee member of the board exercised 25,000 options at an exercise price of \$0.95 per share of common stock for \$23,750 during the three months ended June 30, 2014. One employee of the Company forfeited 25,000 stock options on May 27, 2014.

6. Related Party Transaction

The Company paid one of the Company's directors \$6,000 as of March 31, 2014, all of which was paid as part of his overall compensation of an aggregate of \$85,000 for board and committee service.

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

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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 June 30, 2014 for the 2010 warrants include a weighted average term of 0.7 years, a 5% probability that the warrant exercise price would be reset, volatility of 187.7% and a risk free interest rate of 0.09%. 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 June 30, 2014 for the 2011 warrants include a weighted average term of 1.5 years, a 5% probability that the warrant exercise price would be reset, volatility of 132.7% 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%. At June 30, 2014 there are no remaining 2013 warrants and therefore no associated warrant liability.

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, 2014	\$ 1,302,961	\$	\$	\$ 1,302,961
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 June 30, 2014 follows:

Balance at January 1, 2014	\$ 12,866,572
Issuance of warrants	
Change in fair value of warrants included in earnings	(1,227,992)
Reclassification to APIC due to warrant exercises	(10,335,619)
Balance at June 30, 2014	\$ 1,302,961

8. Litigation*Kleba Shareholder Derivative Lawsuit*

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 to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The special litigation committee 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 "Notice of Settlement") in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Notice of Settlement are the Plaintiff and the Individual Defendants.

On June 6, 2014, the Company, in its capacity as a nominal defendant, entered into a Stipulated Settlement Agreement and Mutual Release (the "Settlement") in the Shareholder Derivative Lawsuit. In addition to the Company and the Individual Defendants, plaintiffs Glenn Kleba and Don B. Dale are parties to the Settlement.

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By entering into the Settlement, the settling parties have resolved the derivative claims to their mutual satisfaction. The Individual Defendants have not admitted the validity of any claims or allegations and the settling plaintiffs have not admitted that any claims or allegations lack merit or foundation. Under the terms of the Settlement, (i) the Executives each agreed (A) to re-pay to the Company \$2.24 Million of the cash bonuses they each 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 Settlement, 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 Settlement; (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 Settlement also requires that each of the Executives enter into new employment agreements with the Company, which were entered into on April 28, 2014, 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 each agreed to pay the Company \$25,000 in cash, subject to reduction by such amount that the Company's insurance carrier pays to the Company on behalf of such defendant pursuant to such defendant's directors and officers liability insurance policy. The Settlement also provides for an award to plaintiffs' counsel of attorneys' fees and reimbursement of expenses in connection with their role in this litigation, subject to Court approval.

On July 24, 2014, the Court approved the terms of the proposed Settlement and awarded \$911,000 to plaintiffs' counsel for attorneys' fees and reimbursement of expenses in connection with their role in the Shareholder Derivative Lawsuit.

Class Action Lawsuits

On May 27, 2014, Cary Farrah and James H. Harrison, Jr., individually and on behalf of all others similarly situated (the Farrah Case), and on May 29, 2014, each of Paul Jason Chaney, individually and on behalf of all others similarly situated (the Chaney Case), and Jayson Dauphinee, individually and on behalf of all others similarly situated (the Dauphinee Case) (the plaintiffs in the Farrah Case, the Chaney Case and the Dauphinee Case collectively referred to as the Plaintiffs), each filed a class action lawsuit in the United States District Court for the Middle District of Tennessee against the Company, H. Craig Dees, Timothy C. Scott and Peter R. Culpepper (the Defendants) alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Specifically, the Plaintiffs in each of the Farrah Case, the Chaney Case and the Dauphinee Case allege that the Defendants are liable for making false statements and failing to disclose adverse facts known to them about the Company, in connection with the Company's application to the FDA for Breakthrough Therapy Designation (BTD) in the Spring of 2014 and the FDA's subsequent denial of the Company's application for BTD. The Company intends to defend vigorously against all claims in these complaints. However, in view of the inherent uncertainties of litigation and the early stage of this litigation, the outcome of these cases cannot be predicted at this time. Likewise, the amount of any potential loss cannot be reasonably estimated.

On July 9, 2014, the Plaintiffs and the Defendants filed joint motions in the Farrah Case, the Chaney Case and the Dauphinee Case to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee entered an order consolidating the Farrah Case, the Chaney Case and the Dauphinee Case (collectively and, as consolidated, the Securities Litigation) and transferred the Securities Litigation to the United States District Court for the Eastern District of Tennessee.

Hurtado Shareholder Derivative Lawsuit

On June 4, 2014, Karla Hurtado (the Plaintiff) derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee (the Court), against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant (the Hurtado Shareholder Derivative Lawsuit). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) abuse of control, both claims based on the Plaintiff s allegations that the Individual Defendants recklessly permitted the Company to disclose false and misleading information and failed to implement adequate controls and procedures to ensure the accuracy of the Company s disclosures.

On July 25, 2014, the court presiding over the Hurtado Shareholder Derivative Lawsuit entered an order transferring the case to the United District Court for the Eastern District of Tennessee. It is anticipated that an order will be entered by agreement that will stay all activity in the Hurtado Shareholder Derivative Lawsuit pending the resolution of an anticipated motion to dismiss the anticipated consolidated amended complaint in the Securities Litigation.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado Shareholder Derivative Lawsuit.

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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 the risk factors contained in Item 1A of Part II of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and 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 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, including our planned phase 3 trial of PV-10 to treat locally advanced cutaneous melanoma.

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 hope 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 and Six Months Ended June 30, 2014 and June 30, 2013

Revenues

We had no revenue during the three and six months ended June 30, 2014 and 2013.

Research and Development

Research and development costs of \$1,025,535 for the three months ended June 30, 2014 included payroll of \$260,901, consulting and contract labor of \$501,191, legal of \$113,758, insurance of \$0, lab supplies and pharmaceutical preparations of \$126,094, rent and utilities of \$21,875, and depreciation expense of \$1,716. Research and development costs of \$778,349 for the three months ended June 30, 2013 included payroll of \$389,821, consulting and contract labor of \$291,055, legal of \$54,460, insurance of \$12,500, lab supplies and pharmaceutical preparations of \$10,810, rent and utilities of \$18,153, and depreciation expense of \$1,550. The decrease in payroll is due to less

employee benefit expenses. The increase in consulting and contract labor is due primarily to preparations for a phase 3 trial for the treatment of melanoma and FDA interaction with respect to PV-10; and increased liver and Moffitt Cancer Center mechanism of action feasibility studies activity. The increase in lab supplies and pharmaceutical preparations is due primarily to preparations for phase 3 melanoma drug supply.

Research and development costs of \$2,183,418 for the six months ended June 30, 2014 included payroll of \$753,159, consulting and contract labor of \$735,449, legal of \$140,229, insurance of \$54,803, lab supplies and pharmaceutical preparations of \$452,504, rent and utilities of \$43,842, and depreciation expense of \$3,432. Research and development costs of \$1,518,865 for the six months ended June 30, 2013 included payroll of \$723,976, consulting and contract labor of \$555,025, legal of \$81,024, insurance of \$87,500, lab supplies and pharmaceutical preparations of \$32,165, rent and utilities of \$36,075, and depreciation expense of \$3,100. The increase in consulting and contract labor is due primarily to preparations for a phase 3 trial for the treatment of melanoma and FDA interaction with respect to PV-10, and increased liver and Moffitt Cancer Center mechanism of action feasibility studies activity. The increase in lab supplies and pharmaceutical preparations is due primarily to producing phase 3 melanoma drug supply, as well as phase 2 liver and meeting requirements for filing New Drug Approval (NDA) application to the FDA.

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General and administrative expenses increased by \$625,863 in the three months ended June 30, 2014 to \$2,966,569 from \$2,340,706 for the three months ended June 30, 2013. General and administrative expenses were very similar for both periods, except for legal expense which increased by approximately \$500,000 primarily due to our NYSE MKT listing and the Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., as well as investor relations and related travel expenses which increased approximately \$150,000 for the three months ended June 30, 2014 versus the three months ended June 30, 2013.

General and administrative expenses increased by \$1,343,404 in the six months ended June 30, 2014 to \$6,022,513 from \$4,679,109 for the six months ended June 30, 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 charged to operations for the value of both stock and warrants issued for services. Additionally, legal expense increased by about \$400,000 primarily due to our NYSE MKT listing and the Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., as well as investor relations and related travel expenses increased approximately \$300,000 for the six months ended June 30, 2014 versus the six months ended June 30, 2013.

Investment Income

Investment income was insignificant in both the three and six months ended June 30, 2014 and 2013.

Gain/Loss on change in fair value of warrant liability

Gain on change in fair value of warrant liability increased by \$2,605,819 in the three months ended June 30, 2014 to \$3,515,025 from \$909,206 for the three months ended June 30, 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 a decrease in our common stock price.

Gain on change in fair value of warrant liability increased by \$1,242,296 in the six months ended June 30, 2014 to \$1,227,992 from a loss of \$14,304 for the six months ended June 30, 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 a decrease in our common stock price.

Liquidity and Capital Resources

Our cash and cash equivalents were \$18,126,036 at June 30, 2014, compared with \$15,696,243 at December 31, 2013. The increase of approximately \$2.4 million was due primarily to \$4.35 million cash received from warrant and stock option exercises and \$4.35 million net proceeds from the sale of our common stock in the six months ended June 30, 2014 offset by \$6.3 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 June 30, 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 Investor. In addition, on April 30, 2014, the Company entered into a Controlled Equity OfferingSM 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 price 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 June 30, 2014. Given our current rate of expenditures and our ability to curtail or defer certain controllable expenditures, we do not anticipate needing 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 strategically monetize PV-10 through appropriate regional license transactions, license PH-10 for psoriasis and other related indications described as inflammatory dermatoses, and also complete the spin-out of Pure-ific Corporation and the other non-core subsidiaries.

We believe that our financial position and corporate governance are such that we will continue to meet the relevant listing requirements of NYSE MKT, although there can be no assurance that we will continue to be listed on NYSE MKT. We believe our efforts to obtain regulatory clarity will be helpful to facilitate such transactions with potential partners. Additionally, the existing and forthcoming clinical and nonclinical mechanism of action data for both PV-10 and PH-10 are expected to further aid in both regulatory clarity and transactions with potential partners. The Company's current cash position is sufficient to meet our obligations. In addition, management is returning \$8.96 million to the Company as a result of the previously announced settlement of a shareholder derivative lawsuit (subject to a 2:1 credit to the executives, such that total actual repayment by the executives may be \$1.12 million per executive which would total \$4.48 million) and we further enhanced our strength by management's recent exercise of options. In total, we have adequate funds to operate without a further injection of capital through well into 2015. We believe the existing cash position of the Company is sufficient to fund our operations through obtaining interim data from the planned phase 3 melanoma study as well as other planned programs including generating key liver data, and clinical mechanism of action data for both PV-10 and PH-10.

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We have provided data on a confidential basis to both potential global and geographic partners for both PV-10 for oncology, and PH-10 for dermatology, via a secure electronic data room. We are encouraged by the number of companies doing due diligence on our technologies. For instance, we recently had a team in India meeting with potential partners and have two teams focused in China working with potential partners there. We also have begun to consider co-development transactions with one or more pharmaceutical or biotech companies to combine PV-10 with immunology agents such as those referred to as checkpoint protein inhibitors. Whenever we obtain a Memorandum of Understanding (MOU), definitive agreement or similar indication of interest from a potential partner, we will issue a press release and Form 8-K filing to notify the market. Furthermore, the strategy of the company for the benefit of shareholders is a series of partnerships followed by an acquisition of the Company along the lines of Celgene/Abraxis, although there can be no assurance that such partnerships or acquisition will occur. The Company is not in discussions regarding the sale of its business and there can be no assurance, however, that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

We have already signed an advisory agreement with China's TriRiver Capital to help identify distribution and joint venture partners for PV-10 in China. This agreement is intended to enhance our reach into China and will bolster our efforts in developing partnering opportunities in various countries in Asia including China, India and Japan, where we have held numerous detailed discussions with pharmaceutical companies over the last year. We are already seeing the results of efforts to enter into partnerships from the activity in our electronic data room. The Company is not in discussions regarding the sale of its business and there can be no assurance, however, that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

The primary financial objective of the Company is to strategically monetize the core value of PV-10 and PH-10 through the various transactions discussed elsewhere in this report. Ultimately, the Company wants to leverage value creation through the sale of the business or a merger that may include upfront cash, acquirer stock, and/or a contingency value right (CVR) as part of the total consideration. A CVR represents the right for its holder to receive certain defined payments upon the achievement of a specified milestone and would be designed to facilitate potential upside for the Company's shareholders on a post-transaction basis. A CVR could trade on an exchange. The Company is not in discussions regarding the sale of its business and there can be no assurance, however, that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

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.

However, we cannot assure you that we will be successful in either licensing of PV-10 or PH-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, even though we do not anticipate needing additional capital to develop PV-10 on our own to treat locally advanced cutaneous melanoma. 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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

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The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017. The Company currently does not have revenues but will consider any related impact going forward.

In June 2014, the FASB issued Accounting Standards Update 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* (ASU 2014-10), which eliminates the concept of a development stage entity (DSE) from U.S. GAAP. This change rescinds certain financial reporting requirements that have historically applied to DSEs and is intended to result in cost-savings for affected entities, such as certain start-up or research and development entities. The new standard also changes one related aspect of the variable interest entity (VIE) consolidation guidance in Topic 810.

ASU 2014-10 is effective for public entities for annual reporting periods beginning after December 15, 2014 and interim periods therein. Early adoption is permitted. We are currently evaluating the impact of our pending adoption of ASU 2014-10 on our consolidated financial statements.

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 \$30,000 as of June 30, 2014.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We had no holdings of financial or commodity instruments as of June 30, 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 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 June 30, 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.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Kleba Shareholder Derivative Lawsuit

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 to investigate the allegations of the Shareholder Derivative Complaint and make a determination as to how the matter should be resolved. The special litigation committee 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 Notice of Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company, the parties to the Notice of Settlement are the Plaintiff and the Individual Defendants.

On June 6, 2014, the Company, in its capacity as a nominal defendant, entered into a Stipulated Settlement Agreement and Mutual Release (the Settlement) in the Shareholder Derivative Lawsuit. In addition to the Company and the Individual Defendants, plaintiffs Glenn Kleba and Don B. Dale are parties to the Settlement.

By entering into the Settlement, the settling parties have resolved the derivative claims to their mutual satisfaction. The Individual Defendants have not admitted the validity of any claims or allegations and the settling plaintiffs have not admitted that any claims or allegations lack merit or foundation. Under the terms of the Settlement, (i) the Executives each agreed (A) to re-pay to the Company \$2.24 Million of the cash bonuses they each 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 Settlement, 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 Settlement; (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 Settlement also requires that each of the Executives enter into new employment agreements with the Company, which were entered into on April 28, 2014, 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 each agreed to pay the Company \$25,000 in cash, subject to reduction by such amount that the Company's insurance carrier pays to

the Company on behalf of such defendant pursuant to such defendant's directors and officers liability insurance policy. The Settlement also provides for an award to plaintiffs' counsel of attorneys' fees and reimbursement of expenses in connection with their role in this litigation, subject to Court approval.

On July 24, 2014, the Court approved the terms of the proposed Settlement and awarded \$911,000 to plaintiffs' counsel for attorneys' fees and reimbursement of expenses in connection with their role in the Shareholder Derivative Lawsuit.

Class Action Lawsuits

On May 27, 2014, Cary Farrah and James H. Harrison, Jr., individually and on behalf of all others similarly situated (the Farrah Case), and on May 29, 2014, each of Paul Jason Chaney, individually and on behalf of all others similarly situated (the Chaney Case), and Jayson Dauphinee, individually and on behalf of all others similarly situated (the Dauphinee Case) (the plaintiffs in the Farrah Case, the Chaney Case and the Dauphinee Case collectively referred to as the Plaintiffs), each filed a class action lawsuit in the United States District Court for the Middle District of Tennessee against the Company, H. Craig Dees, Timothy C. Scott and Peter R. Culpepper (the Defendants) alleging violations by the Defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder.

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Specifically, the Plaintiffs in each of the Farrah Case, the Chaney Case and the Dauphinee Case allege that the Defendants are liable for making false statements and failing to disclose adverse facts known to them about the Company, in connection with the Company's application to the FDA for Breakthrough Therapy Designation (BTD) in the Spring of 2014 and the FDA's subsequent denial of the Company's application for BTD. The Company intends to defend vigorously against all claims in these complaints. However, in view of the inherent uncertainties of litigation and the early stage of this litigation, the outcome of these cases cannot be predicted at this time. Likewise, the amount of any potential loss cannot be reasonably estimated.

On July 9, 2014, the Plaintiffs and the Defendants filed joint motions in the Farrah Case, the Chaney Case and the Dauphinee Case to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee entered an order consolidating the Farrah Case, the Chaney Case and the Dauphinee Case (collectively and, as consolidated, the Securities Litigation) and transferred the Securities Litigation to the United States District Court for the Eastern District of Tennessee.

Hurtado Shareholder Derivative Lawsuit

On June 4, 2014, Karla Hurtado (the Plaintiff) derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee (the Court), against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants), and against the Company as a nominal defendant (the Hurtado Shareholder Derivative Lawsuit). The Hurtado Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) abuse of control, both claims based on the Plaintiff's allegations that the Individual Defendants recklessly permitted the Company to disclose false and misleading information and failed to implement adequate controls and procedures to ensure the accuracy of the Company's disclosures.

On July 25, 2014, the court presiding over the Hurtado Shareholder Derivative Lawsuit entered an order transferring the case to the United District Court for the Eastern District of Tennessee. It is anticipated that an order will be entered by agreement that will stay all activity in the Hurtado Shareholder Derivative Lawsuit pending the resolution of an anticipated motion to dismiss the anticipated consolidated amended complaint in the Securities Litigation.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado Shareholder Derivative Lawsuit.

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, as supplemented by the risk factors disclosed in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, other than the additional disclosure of the risk factors listed below.

We may not obtain or maintain the benefits associated with breakthrough therapy designation.

On March 21, 2014, we submitted a request for breakthrough therapy designation (BTD) to the FDA for PV-10 in the treatment of metastatic melanoma in the United States. The FDA denied the request in May 2014, but stated that a new request may be submitted if we obtain new clinical evidence that supports BTD. Accordingly, we are not entitled to the benefits of BTD, including expedited development and review of PV-10 in the treatment of melanoma.

If we resubmit such request for BTM, we may not be granted BTM, or even if granted, we may not receive the benefits associated with BTM. This may result from a failure to maintain breakthrough therapy status if PV-10 is no longer considered to be a breakthrough therapy. For example, a drug s development program may be granted BTM using early clinical testing that shows a much higher response rate than available therapies. However, subsequent interim data derived from a larger study may show a response that is substantially smaller than the response seen in early clinical testing. Another example is where BTM is granted to two drugs that are being developed for the same use. If one of the two drugs gains traditional approval, the other would not retain its designation unless its sponsor provided evidence that the drug may demonstrate substantial improvement over the recently approved drug. When BTM is no longer supported by emerging data or the designated drug development program is no longer being pursued, the FDA may choose to send a letter notifying the sponsor that the program is no longer designated as a BTM program.

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We depend on the successful completion of clinical trials for our product candidates, including PV-10. The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.

Before obtaining regulatory approval for the sale of our product candidates, including PV-10, we must conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

In October 2012, we presented final top-line data from the Phase 2 trial of PV-10 for metastatic melanoma, and in March 2014, applied for BTM with the FDA, which was subsequently denied pending new clinical evidence that supports BTM. We (i) are conducting an expanded phase 1 trial for PV-10 for metastatic liver cancer, which is expected to be completed in 2014; (ii) have completed a phase 1 clinical study for PV-10 for recurrent breast cancer; (iii) are conducting a phase 1 trial for PV-10 in an investigator initial study to ascertain the feasibility of detecting immune cell infiltrates in injected melanoma tumors; (iv) are conducting a phase 2c clinical trial for PH-10 for psoriasis; (v) have completed a Phase 2 clinical trial for PH-10 for atopic dermatitis; and (vi) plan to conduct a phase 3 clinical trial to assess response to intralesional PV-10 versus that of systemic chemotherapy in patients with disease confined to cutaneous and subcutaneous sites. Meetings with scientific advisors, investigators and advocates in the field have led us to expect a starting date for the phase 3 study sometime in the second half of 2014. However, we have never conducted a phase 3 clinical trial. The positive results we have seen to date in our phase 2 clinical trials of PV-10 for metastatic melanoma do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

We may experience a number of unforeseen events during clinical trials for our product candidates, including PV-10, that could delay or prevent the commencement and/or completion of our clinical trials, including the following:

regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

the clinical study protocol may require one or more amendments delaying study completion;

clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;

clinical investigators or study subjects fail to comply with clinical study protocols;

trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or labeling errors;

our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

the cost of clinical trials of our product candidates may be greater than we anticipate;

the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly if we commence a phase 3 clinical trial with respect to PV-10 as planned, and undertake additional clinical trials of our other product candidates. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development; however, we believe we have sufficient cash on hand to fund the planned phase 3 trial with respect to PV-10.

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Negative or inconclusive results of our future clinical trials of PV-10, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for PV-10, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates, including PV-10. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, including PV-10, may be adversely impacted.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in delays or unsuccessful completion of clinical trials, including our future clinical trials for PV-10, include the following:

inability to raise funding, if necessary, to initiate or continue a trial;

delays in obtaining regulatory approval to commence a trial;

delays in reaching agreement with the FDA on final trial design;

imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;

delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;

delays in obtaining required institutional review board (IRB) approval at each site;

delays in recruiting suitable patients to participate in a trial;

delays in having subjects complete participation in a trial or return for post-treatment follow-up;

delays caused by subjects dropping out of a trial due to side effects or otherwise;

delays caused by clinical sites dropping out of a trial;

time required to add new clinical sites; and

delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials. If initiation or completion of any of our clinical trials for our product candidates, including PV-10, are delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

We are subject to securities class action lawsuits that could adversely affect our business. This litigation, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business.

Beginning on May 27, 2014, three putative securities class action lawsuits were commenced in the United States District Court for the Middle District of Tennessee against us, and certain of our officers and directors, alleging violations by the defendants of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, together called the federal class actions. The federal class actions allege, among other things, that the defendants made false and materially misleading statements and failed to disclose material information regarding our application to the FDA for BTB.

On July 9, 2014, the plaintiffs and the defendants filed joint motions in the federal class actions to consolidate the cases and transfer them to United States District Court for the Eastern District of Tennessee. By order dated July 16, 2014, the United States District Court for the Middle District of Tennessee entered an order consolidating the federal class actions and transferred the federal class actions to the United States District Court for the Eastern District of Tennessee.

In addition, on June 4, 2014, a shareholder derivative lawsuit captioned *Hurtado v. Provectus Biopharmaceuticals, Inc., et al.*, was filed derivatively on behalf of the Company in the United States District Court for the Middle District of Tennessee (the *Hurtado Shareholder Derivative Lawsuit*). The *Hurtado Shareholder Derivative Lawsuit* alleges (i) breach of fiduciary duties, and (ii) abuse of control, both claims based on the Plaintiff's allegations that the Individual Defendants recklessly permitted the Company to disclose false and misleading information and failed to implement adequate controls and procedures to ensure the accuracy of the Company's disclosures.

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On July 25, 2014, the court presiding over the Hurtado Shareholder Derivative Lawsuit entered an order transferring the case to the United District Court for the Eastern District of Tennessee. It is anticipated that an order will be entered by agreement that will stay all activity in the Hurtado Shareholder Derivative Lawsuit pending the resolution of an anticipated motion to dismiss the anticipated consolidated amended complaint in the federal class actions.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado Shareholder Derivative Lawsuit.

We intend to defend these actions vigorously. We are currently unable to estimate a range of payments if any, we may be required to pay, or may agree to pay, with respect to the federal class actions and the Hurtado Shareholder Derivative Lawsuit. We believe, however, that the resolution of these suits will not result in a material adverse effect to our consolidated financial statements. However, due to the inherent uncertainties that accompany litigation of this nature, there can be no assurance that we will be successful, and an adverse resolution of any of the lawsuits could have a material adverse effect on our consolidated financial statements. Furthermore, these actions may divert management's time and attention from our business, and we could be forced to expend significant resources and pay significant costs and expenses, including legal fees, in connection with defending the lawsuits.

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.

During the three months ended June 30, 2014, the Company issued 202,000 warrants to consultants in exchange for services.

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.

During the three months ended June 30, 2014 the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$5,000,000. The Company accepted subscriptions, in the aggregate, for 2,000,000 shares of common stock and five year warrants to purchase 2,000,000 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 used 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 \$650,000 and issued five year fully vested warrants to purchase 300,000 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.

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(a)(2) of the Securities Act and Regulation D promulgated thereunder.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

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No.	Description
10.1	Controlled Equity Offering SM Sales Agreement, dated April 30, 2014, by and between Provectus Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 to the Company's Item 1.01 Current Report on Form 8-K filed on April 30, 2014)
10.2	Amended and Restated Executive Employment Agreement by and between the Company and H. Craig Dees, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.3	Amended and Restated Executive Employment Agreement by and between the Company and Timothy C. Scott, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.2 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.4	Amended and Restated Executive Employment Agreement by and between the Company and Eric A. Wachter, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.3 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.5	Amended and Restated Executive Employment Agreement by and between the Company and Peter R. Culpepper, dated April 28, 2014 (incorporated by reference to Exhibit 10.4 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.6**	Stipulated Settlement Agreement and Mutual Release, dated June 6, 2004, by and among the Company as nominal defendant, H. Craig Dees, Timothy C. Scott, Eric A. Wachter, Peter R. Culpepper, Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV, as defendants, and Glenn Kleba and Don B. Dale, as plaintiffs (Exhibits Omitted)
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.

** Filed herewith.

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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.

August 7, 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)

Table of Contents**EXHIBIT INDEX****Exhibit**

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10.1	Controlled Equity Offering SM Sales Agreement, dated April 30, 2014, by and between Provectus Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 to the Company's Item 1.01 Current Report on Form 8-K filed on April 30, 2014)
10.2	Amended and Restated Executive Employment Agreement by and between the Company and H. Craig Dees, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.3	Amended and Restated Executive Employment Agreement by and between the Company and Timothy C. Scott, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.2 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.4	Amended and Restated Executive Employment Agreement by and between the Company and Eric A. Wachter, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.3 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.5	Amended and Restated Executive Employment Agreement by and between the Company and Peter R. Culpepper, dated April 28, 2014 (incorporated by reference to Exhibit 10.4 to the Company's Item 5.02 Current Report on Form 8-K filed on April 30, 2014)
10.6**	Stipulated Settlement Agreement and Mutual Release, dated June 6, 2004, by and among the Company as nominal defendant, H. Craig Dees, Timothy C. Scott, Eric A. Wachter, Peter R. Culpepper, Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV, as defendants, and Glenn Kleba and Don B. Dale, as plaintiffs (Exhibits Omitted)
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.

** Filed herewith.