PROVECTUS BIOPHARMACEUTICALS, INC. Form 10-Q November 05, 2015 Table of Contents

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

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

For the quarterly period ended September 30, 2015

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

90-0031917 (I.R.S. Employer

incorporation or organization)

**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. x 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). x 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

X

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 x No

The number of shares outstanding of the registrant s common stock, par value \$.001 per share, as of September 30, 2015, was 204,637,136.

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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, terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to differ materially 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, 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 the fully enrolled phase 3 trial of PV-10 to treat locally advanced cutaneous melanoma and the costs associated with such a trial if it is necessary to complete (versus interim data alone);

our determination whether to license PV-10, our investigational drug product for melanoma and other solid tumors such as cancers of the liver, 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 cancers of the liver:

our ability to license PH-10, our investigational drug product for dermatology, 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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## PART I FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

PROVECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	ptember 30, 2015 Unaudited)	December 31, 201 (Audited)	
Assets			
Current Assets			
Cash and cash equivalents	\$ 18,883,662	\$	17,391,601
Short-term receivable - settlement			733,333
Other current assets	1,065,956		978,000
Total Current Assets	19,949,618		19,102,934
Equipment and furnishings, less accumulated depreciation of \$447,532			
and \$437,863, respectively	88,641		92,171
Patents, net of amortization of \$8,635,077 and \$8,131,737, respectively	3,080,368		3,583,708
Long-term receivable - settlement, net of discount	3,458,450		3,378,345
Other assets	27,000		27,000
	\$ 26,604,077	\$	26,184,158
Liabilities and Stockholders Equity Current Liabilities Accounts payable trade	\$ 972,693	\$	440,702
Accrued consulting expense	227,582		91,282
Accrued compensation	572,436		
Other accrued expenses	292,356		315,738
Warrant liability	9,573		
Total Current Liabilities	2,074,640		847,722
Long-Term Liability			
Warrant liability			146,560
Total Liabilities	2,074,640		994,282
Stockholders Equity Preferred stock; par value \$.001 per share; 25,000,000 shares authorized; no shares outstanding as of September 30, 2015 and December 31, 2014			
Common stock; par value \$.001 per share; 300,000,000 authorized; 204,637,136 and 184,796,275 shares issued and outstanding,	204,637		184,796

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respectively		
Paid-in capital	195,468,719	181,298,890
Accumulated deficit	(171,143,919)	(156,293,810)
Total Stockholders Equity	24,529,437	25,189,876
	\$ 26,604,077 \$	26,184,158

See accompanying notes to condensed consolidated financial statements.

# PROVECTUS BIOPHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	 ree Months Ended ember 30, 2015	hree Months Ended ember 30, 2014	line Months Ended ember 30, 2015	line Months Ended ember 30, 2014
Operating expenses				
Research and development	\$ 2,696,551	\$ 1,358,102	\$ 7,034,100	\$ 3,541,520
General and administrative	2,914,375	2,299,799	7,453,401	8,322,312
Amortization	167,780	167,780	503,340	503,340
Total operating loss	(5,778,706)	(3,825,681)	(14,990,841)	(12,367,172)
Investment income	1,260	1,410	3,745	4,226
(Loss) gain on change in fair value of warrant liability	(2,607)	75,724	136,987	1,303,716
Net loss	\$ (5,780,053)	\$ (3,748,547)	\$ (14,850,109)	\$ (11,059,230)
Basic and diluted loss per common share	\$ (0.03)	\$ (0.02)	\$ (0.08)	\$ (0.06)
Weighted average number of common shares outstanding basic and diluted	204,610,080	179,088,989	192,604,128	173,729,010

See accompanying notes to condensed consolidated financial statements.

# PROVECTUS BIOPHARMACEUTICALS, INC.

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(Unaudited)

	Common	Stock			
	Number of		Paid in	Accumulated	
	Shares	Par Value	capital	Deficit	Total
Balance, at December 31, 2014	184,796,275	\$ 184,796	\$ 181,298,890	\$ (156,293,810)	\$ 25,189,876
Issuance of stock for services	228,877	229	165,210		165,439
Issuance of warrants for services			79,476		79,476
Cash proceeds from exercise of					
warrants and stock options	324,884	325	290,503		290,828
Issuance of common stock and					
warrants pursuant to Regulation D	1,787,100	1,787	1,552,990		1,554,777
Issuance of common stock and					
warrants pursuant to underwritten					
registered public offering	17,500,000	17,500	12,081,650		12,099,150
Net loss for the nine months ended					
September 30, 2015				(14,850,109)	(14,850,109)
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Balance, at September 30, 2015	204,637,136	\$ 204,637	\$ 195,468,719	\$ (171,143,919)	\$ 24,529,437

See accompanying notes to condensed consolidated financial statements.

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# PROVECTUS BIOPHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Unaudited)

	ine Months Ended ember 30, 2015	Nine Months Ended September 30, 2014		
Cash Flows From Operating Activities				
Net loss	\$ (14,850,109)	\$	(11,059,230)	
Adjustments to reconcile net loss to net cash used in operating				
activities				
Depreciation	9,669		5,148	
Amortization of patents	503,340		503,340	
Compensation through issuance of stock options			115,645	
Issuance of stock for services	165,439		346,250	
Issuance of warrants for services	79,476		1,354,508	
Gain on change in fair value of warrant liability	(136,987)		(1,303,716)	
(Increase) decrease in assets				
Settlement receivable	653,228			
Other current assets	(87,956)			
Increase in liabilities				
Accounts payable	531,991		129,331	
Accrued expenses	685,354		238,784	
Net cash used in operating activities	(12,446,555)		(9,669,940)	
Cash Flows From Investing Activities				
Capital expenditures	(6,139)		(70,590)	
	(-,,		(,,	
Net cash provided by investing activities	(6,139)		(70,590)	
Cash Flows From Financing Activities				
Net proceeds from sales of common stock and warrants	13,653,927		7,470,081	
Proceeds from exercises of warrants and stock options	290,828		4,347,886	
•				
Net cash provided by financing activities	13,944,755		11,817,967	
Net change in cash and cash equivalents	\$ 1,492,061	\$	2,077,437	
Cash and cash equivalents, at beginning of period	17,391,601		15,696,243	
Cash and cash equivalents, at end of period	\$ 18,883,662	\$	17,773,680	

Supplemental Disclosure of Noncash Investing and Financing Activities:

During the nine months ended September 30, 2014, the Company has reclassified \$10,335,619 from warrant liability to equity due to the exercise of a portion of our outstanding warrants into shares of common stock.

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 nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The Company has evaluated subsequent events through the date the condensed consolidated financial statements were issued.

## 2. Nature of Operations

Provectus Biopharmaceuticals, Inc., a Delaware corporation, is a biopharmaceutical company whose planned principal operations is focusing on developing minimally invasive products for the treatment of psoriasis and other topical diseases, and certain forms of cancer including melanoma, breast cancer, and cancers of the liver. To date, the Company has no revenues from planned principal operations. The Company s activities are subject to significant risks and uncertainties, including failing to successfully develop and license or commercialize the Company s investigational drugs, or sell or license the Company s OTC products or non-core technologies.

#### 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 as they are antidilutive. Potential common shares excluded from the calculation at September 30, 2015 and 2014, respectively, relate to 78,607,893 and 60,240,698 from warrants, and 9,545,214 and 13,868,334 from options.

## 4. Equity Transactions

(a) During the three months ended March 31, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$64,000. 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 June 30, 2015, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$63,000. 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 September 30, 2015, the Company issued 78,877 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$38,439. During the three months ended September 30, 2014, the Company issued 75,000 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$68,500.

(b) During the three months ended March 31, 2015, the Company issued 3,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$1,632. During the three months ended March 31, 2015, 3,693,898 warrants were forfeited. During the three months ended March 31, 2014, the Company issued 733,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$900,317. During the three months ended March 31, 2014, 121,500 warrants were forfeited. During the three months ended March 31, 2014, 12,522,198 warrants were exercised on a cashless basis resulting in 9,100,824 common shares being issued. During the three months ended March 31, 2014, 3,036,218 warrants were exercised for \$2,672,364 resulting in 3,036,218 common shares issued.

During the three months ended June 30, 2015, the Company issued 100,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$53,582. During the three months ended June 30, 2015, 1,161,790 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 September 30, 2015, the Company issued 79,500 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$24,262. During the three months ended September 30, 2015, 1,152,135

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warrants were forfeited. During the three months ended September 30, 2014, the Company issued 6,000 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$4,189. During the three months ended September 30, 2014, 228,500 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, 2015, there was a gain recognized from the revaluation of the warrant liability of \$14,275. For the three months ended March 31, 2014, there was a loss recognized from the revaluation of the warrant liability of \$1,153,835. For the three months ended June 30, 2015 and 2014, there was a gain recognized from the revaluation of the warrant liability of \$45,568 and \$186,262, respectively. For the three months ended September 30, 2015 and 2014, there was a loss recognized from the revaluation of the warrant liability of \$2,607 and \$16,734, respectively.
- (d) In March and April 2010, the Company issued 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, 2015, there was a gain recognized from the revaluation of the warrant liability of \$79,751. For the three months ended March 31, 2014, there was a loss recognized from the revaluation of the warrant liability of \$211,422. During the three months ended March 31, 2015, the remaining warrants included in the warrant liability were forfeited. There were no outstanding 2010 warrants at March 31, 2015 and therefore there is no gain or loss for the three months ended June 30, 2015 or the three months ended September 30, 2015. For the three months ended June 30, 2014, there was a gain recognized from the revaluation of the warrant liability of \$3,285,793. For the three months ended September 30, 2014, there was a gain recognized from the revaluation of the warrant liability of \$92,458.
- (e) In February 2013, the Company issued 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 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. There were no outstanding 2013 warrants at December 31, 2014 and therefore there is no gain or loss for the three months ended March 31, 2015, the three months ended June 30, 2015, or the three months ended September 30, 2015. For the three months ended March 31, 2014, there was a loss recognized from the

revaluation of the warrant liability of \$921,776. For the three months ended June 30, 2014, there was a gain recognized from the revaluation of the warrant liability of \$42,970. There were no outstanding 2013 warrants at June 30, 2014 and therefore there was no gain or loss for the three months ended September 30, 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. In 2014, the Company recognized no dividends because of the conversion of all outstanding shares of preferred stock to common stock as of January 15, 2014.
- (g) During the three months ended March 31, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$776,000. The Company received subscriptions, in the aggregate, for 776,000 shares of common stock and five year warrants to purchase 388,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$100,880 and issued five year fully vested warrants to purchase 77,600 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the

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total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc. During the three months ended June 30, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$1,011,100. The Company received subscriptions, in the aggregate, for 1,011,100 shares of common stock and five year warrants to purchase 505,550 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$131,443 and issued five year fully vested warrants to purchase 101,110 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

(h) On June 24, 2015, the Company completed a public offering of common stock and warrants for gross proceeds of \$13,151,250 (the Offering ). The Offering consisted of 17,500,000 shares of common stock and warrants to purchase 17,500,000 shares of common stock with a public offering price of \$0.75 for a fixed combination of one share of common stock and a warrant to purchase one share 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 \$0.85 per share. At the closing, the underwriters exercised their over-allotment option with respect to warrants to purchase up to an additional 2,625,000 shares of common stock at \$0.01 per warrant. The warrants issued in the Offering began trading on the NYSE MKT on June 22, 2015, under the ticker symbol PVCTWS. The Company plans to use the proceeds of the Offering for clinical development, working capital and general corporate purposes. Maxim Group LLC acted as sole book-running manager for the Offering. In connection with the Offering, the Company paid \$1,052,100 to Maxim Group LLC. As of September 30, 2015, 20,125,000 tradable warrants are outstanding.

#### 5. Stock-Based Compensation

One employee of the Company exercised 185,000 options at an exercise price of \$1.02 per share of common stock for \$188,700 during the three months ended March 31, 2015. Another employee of the Company exercised 76,764 options at an exercise price of \$0.64 per share of common stock for \$49,129 during the three months ended March 31, 2015. Another employee of the Company exercised 33,334 options at an exercise price of \$0.75 per share of common stock for \$25,000 and 29,786 options at an exercise price of \$0.94 per share of common stock for \$27,999 during the three months ended March 31, 2015. One employee of the Company forfeited 300,000 stock options on January 7, 2015. 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.

Two employees and a former non-employee member of the board of the Company each forfeited 25,000 stock options on May 19, 2015 for a total of 75,000 options. Two employees of the Company each forfeited 300,000 stock options on May 25, 2015 for a total of 600,000 options. 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. 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.

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In determining the appropriate levels, the Company performs a detailed analysis of the assets and liabilities that are measured and reported on a fair value basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs are classified as Level 3. The fair value of certain of the Company s financial instruments, including cash and cash equivalents and accounts payable, approximates the carrying value due to the relatively short maturity of such instruments. The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. The warrant liability is a derivative instrument and is classified as Level 3. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants. Significant assumptions used are as follows:

	<b>September 30, 2015</b>
2011 Warrants:	-
Weighted average term	0.3 years
Probability the warrant exercise price would be	
reset	5%
Volatility	83.83%
Risk free interest rate	0.01%

At September 30, 2015 there are no remaining 2013 and 2010 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 September 30, 2015	\$ 9,573	\$	\$	\$ 9,573
Warrant liability at December 31, 2014	\$ 146,560	\$	\$	\$ 146,560

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, 2015 to September 30, 2015 follows:

Balance at January 1, 2015	\$ 1	46,560
Issuance of warrants		
Change in fair value of warrants included in earnings	(1	36,987)
Exercise of warrants		
Balance at September 30, 2015	\$	9,573

## 7. Litigation

Kleba Shareholder Derivative Lawsuit

On January 2, 2013, Glenn Kleba, 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 alleged (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on Mr. Kleba 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 Mr. Kleba 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 February 21, 2014, an Amended Shareholder Derivative Complaint was filed which added Don B. Dale (Mr. Dale) as a plaintiff.

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 Mr. Kleba, Mr. Dale 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. The payment to plaintiff s counsel was made by the Company during October 2014 and is still recorded as other current assets at September 30, 2015 and December 31, 2014. The Company is seeking reimbursement of the full amount from insurance and if the full amount is not received from insurance, the amount remaining will be reimbursed to the Company from the Individual Defendants.

On October 3, 2014, the Settlement was effective and stock options for Drs. Dees and Scott and Mr. Culpepper were rescinded, totaling 2,800,000. \$733,333 was repaid by the Executives as of September 30, 2015. The first year payment due has been paid. The remaining cash settlement amounts will continue to be repaid to the Company over a period of four years with the second payment due in total by October 2016 and the final payment is expected to be received by October 3, 2019. \$80,105 of the settlement discount was amortized as of September 30, 2015. The remaining balance due the Company as of September 30, 2015 is \$3,746,667 with a present value discount remaining of \$288,217.

#### 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) of the Company s melanoma drug, PV-10, in the Spring of 2014, and the FDA s subsequent denial of the Company s

application for BTD.

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.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint) in the Class Action Case, alleging that Provectus and the other individual defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTD, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

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On June 5, 2015, Provectus filed its Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss ). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response ). Pursuant to order of the Court, Provectus replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015, and discussions are continuing.

If the mediation is unsuccessful at resolving the Securities Litigation, the Company intends to defend vigorously against all claims in the Consolidated Complaint. However, in view of the inherent uncertainties of litigation and the early stage of this litigation, the outcome of the Class Action Case cannot be predicted at this time. Likewise, the amount of any potential loss cannot be reasonably estimated. No amounts have been recorded in the consolidated financial statements as the outcome of the Class Action Case cannot be predicted and the amount of any potential loss is not estimable at this time.

## Hurtado Shareholder Derivative Lawsuit

On June 4, 2014, Karla Hurtado, derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee 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 Ms. Hurtado s allegations that the Individual Defendants (a) recklessly permitted the Company to make false and misleading disclosures and (b) failed to implement adequate controls and procedures to ensure the accuracy of the Company's disclosures.

On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the case to the United States District Court for the Eastern District of Tennessee and, in light of the pending Securities Litigation, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado Shareholder Derivative Lawsuit pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

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

#### Montiminy Shareholder Derivative Lawsuit

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit ) against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ). Like the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) gross mismanagement of the assets and business of the Company, both claims based on Mr. Montiminy s allegations that the Individual Defendants recklessly permitted the Company to make certain false and misleading disclosures regarding the likelihood that the Company s melanoma drug, PV-10, would qualify for BTD. As a practical matter, the factual allegations and requested relief in the Montiminy Shareholder Derivative Lawsuit are substantively the same as those in the Hurtado Shareholder Derivative Lawsuit.

On December 29, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order consolidating the Hurtado Shareholder Derivative Lawsuit and the Montiminy Derivative Lawsuit. On February 25, 2015, the parties submitted a proposed agreed order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits until the Court issues a ruling on the anticipated motion to dismiss the amended consolidated complaint to be filed in the Securities Litigation. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As in the Hurtado Shareholder Derivative Lawsuit, no relief is sought against the Company itself; the action is against the Individual Defendants only.

Foley Shareholder Derivative Lawsuit

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee 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 Foley Shareholder Derivative Lawsuit). The Foley Shareholder Derivative Lawsuit was brought by the same attorney as the Montiminy Shareholder Derivative Lawsuit, Paul Kent Bramlett of Bramlett Law Offices. Other than the difference in the named plaintiff, the complaints in the Foley Shareholder Derivative Lawsuit and the Montiminy Shareholder Derivative Lawsuit are identical. On March 6, 2015, the Chancery Court of Knox County, Tennessee entered an Order staying the Foley Derivative Lawsuit until the United States District Court for the Eastern District of Tennessee issues a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

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As in the Hurtado and Montiminy Shareholder Derivative Lawsuits, no relief is sought against the Company itself; the action is against the Individual Defendants only.

Donato Shareholder Derivative Lawsuit

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee 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 Donato Shareholder Derivative Lawsuit). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company s purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA. We are not in a position at this time to give you an evaluation of the likelihood of an unfavorable outcome, or an estimate of the amount or range of potential loss to the Company.

## 8. Subsequent Events

The Company has evaluated subsequent events through the date of the filing of these financial statements. On October 1, 2015, the Company s stockholders approved an amendment to the Company s certificate of incorporation to increase the number of shares of common stock the Company is authorized to issue from 300,000,000 to 400,000,000 shares.

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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, Cautionary Note Regarding Forward-Looking Statements preceding the accompanying unaudited financial statements, our Annual Report on Form 10-K for the year ended December 31, 2014 ( 2014 Form 10-K ), which includes additional information about our critical accounting policies and practices and risk factors, and Item 1A of Part II of this report. 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 ethical pharmaceutical products and continued execution of research programs for new and existing 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 totaling 60 full-time equivalents, 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 rapid recruitment for our phase 3 trial of PV-10 to treat locally advanced cutaneous melanoma as well as other randomized studies of PV-10 and PH-10 in solid tumors and inflammatory dermatoses, respectively.

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 promising to treat serious cancers and diseases of the skin, respectively. Both investigational drugs are first-in-class within the halogenated xanthene class of compounds that our intellectual property protects. Also, important immunologic data with PV-10 has been corroborated and characterized by institutions such as Moffitt Cancer Center in Tampa, Florida and University of Illinois - Chicago. We continue to develop clinical trials for these products to demonstrate 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 stockholder value this year and beyond.

## **Results of Operations**

## Comparison of Three and Nine Months Ended September 30, 2015 and September 30, 2014

Revenues

We had no revenue during the three and nine months ended September 30, 2015 and 2014.

Research and Development

Research and development costs of \$2,696,551 for the three months ended September 30, 2015 included payroll of \$542,851, consulting and contract labor of \$1,538,362, legal of \$11,664, insurance of \$60,598, lab supplies and pharmaceutical preparations of \$517,529, rent and utilities of \$22,256, and depreciation expense of \$3,291. Research

and development costs of \$1,358,102 for the three months ended September 30, 2014 included payroll of \$272,088, consulting and contract labor of \$721,878, legal of \$145,342, insurance of \$57,099, lab supplies and pharmaceutical preparations of \$138,066, rent and utilities of \$21,913, and depreciation expense of \$1,716. The overall increase in research and development costs is due primarily to an increase of approximately \$820,000 in consulting and contract labor as well as approximately \$400,000 in lab supplies and pharmaceutical preparations due to the phase 3 study of PV-10 in locally advanced cutaneous melanoma and the phase 2 study of PH-10 mechanism of action, both of which commenced in the quarter ended March 31, 2015, as well as the phase 1b/2 study of PV-10 in combination with pembrolizimab which commenced in the quarter ended September 30, 2015, and is also due to approximately \$523,000 in increased payroll expense.

Research and development costs of \$7,034,100 for the nine months ended September 30, 2015 included payroll of \$1,372,200, consulting and contract labor of \$4,142,207, legal of \$222,623, insurance of \$127,432, lab supplies and pharmaceutical preparations of \$1,096,333, rent and utilities of \$63,636, and depreciation expense of \$9,669. Research and development costs of \$3,541,520 for the nine months ended September 30, 2014 included payroll of \$1,025,247, consulting and contract labor of \$1,457,327, legal of \$285,571, insurance of \$111,902, lab supplies and pharmaceutical preparations of \$590,570, rent and utilities of \$65,755, and depreciation expense of \$5,148. The overall increase in research and development costs is due primarily to an increase of approximately \$2.7 million in consulting and contract labor as well as approximately \$500,000 in lab supplies and pharmaceutical

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preparations due to the phase 3 study of PV-10 in locally advanced cutaneous melanoma and the phase 2 study of PH-10 mechanism of action, both of which commenced in the quarter ended March 31, 2015, as well as the phase 1b/2 study of PV-10 in combination with pembrolizimab which commenced in the quarter ended September 30, 2015, and is also due to approximately \$523,000 in increased payroll expense.

#### General and Administrative

General and administrative expenses increased by \$614,576 in the three months ended September 30, 2015 to \$2,914,375 from \$2,299,799 for the three months ended September 30, 2014. General and administrative expenses were very similar for both periods; however, approximately \$200,000 in increased expense is due to additional administrative consulting and conference expense, approximately \$174,000 in increased payroll expense, approximately \$150,000 in increased expense is due to additional travel related expenses, and approximately \$100,000 in increased expense is due to additional corporate legal expense in the three months ended September 30, 2015 versus the three months ended September 30, 2014.

General and administrative expenses decreased by \$868,911 in the nine months ended September 30, 2015 to \$7,453,401 from \$8,322,312 for the nine months ended September 30, 2014. General and administrative expenses were very similar for both periods; however, approximately \$1.5 million in decreased expense is due to lower stock prices during the nine months ended September 30, 2015 versus the nine months ended September 30, 2014. This resulted in lower noncash share-based expenses related to stock and warrants issued for services, in addition to the substantial reduction in the number of warrants issued for services. This was offset by approximately \$500,000 in increased expense due to additional travel related expenses and approximately \$174,000 in increased payroll expense during the nine months ended September 30, 2015 versus the nine months ended September 30, 2014.

#### Investment Income

Investment income was insignificant in both the three and nine months ended September 30, 2015 and 2014.

Gain/Loss on change in fair value of warrant liability

The change in fair value of warrant liability decreased by \$78,331 in the three months ended September 30, 2015 to a loss of \$2,607 from a gain of \$75,724 for the three months ended September 30, 2014. This activity results from accounting for the warrant liability described in Footnotes 4(c), 4(d) and 4(e) to the financial statements.

The change in fair value of warrant liability decreased by \$1,166,729 in the nine months ended September 30, 2015 to a gain of \$136,987 from a gain of \$1,303,716 for the nine months ended September 30, 2014. This activity results from accounting for the warrant liability described in Footnotes 4(c), 4(d) and 4(e) to the financial statements.

## **Liquidity and Capital Resources**

Our cash and cash equivalents were \$18,883,662 at September 30, 2015, compared with \$17,391,601 at December 31, 2014. The increase of approximately \$1.5 million was due primarily to the \$13.6 million in cash we received from the sale of our common stock and warrants and \$300,000 in cash received from warrant and stock option exercises in the nine months ended September 30, 2015 offset by \$12.4 million in cash used to fund our operating activities for the nine months ended September 30, 2015. We completed the sale and issuance of common stock and warrants because we are seeking to strengthen our financial condition while we seek to minimize dilution to our existing stockholders, where practicable.

By managing variable cash expenses due to minimal fixed costs, we believe our cash and cash equivalents on hand at September 30, 2015 will be sufficient to meet our current and planned operating needs into 2017 without consideration being given to additional cash inflows that might occur from the exercise of existing warrants or future sales of equity securities. Additionally, we may, in our sole discretion, direct Alpha Capital Anstalt ( Investor ) to purchase up to an additional \$10,000,000 of our common stock per an existing agreement with the Investor. In addition, on April 30, 2014, we entered into a Controlled Equity Offering SM Sales Agreement with Cantor Fitzgerald & Co., as sales agent ( Cantor ), under which we may issue and sell shares of our common stock having an aggregate offering 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 September 30, 2015. 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, metastatic melanoma utilizing a combination strategy with PV-10 and agents described in our patent allowance, which is jointly owned by Pfizer, recurrent breast cancer, bladder cancer, lung 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, although there can be no assurance that we will enter into any such transactions.

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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 transactions with potential partners. Additionally, we expect that the existing and forthcoming clinical and nonclinical mechanism of action data for both PV-10 and PH-10 will further aid in both regulatory clarity and transactions with potential partners. The Company s current cash position is sufficient to meet our obligations. In total, we have adequate funds to operate without a further injection of capital into 2017. We believe the existing cash position of the Company is sufficient to fund our operations through obtaining interim data and potentially complete data from the planned phase 3 melanoma study as well as other planned programs including generating key liver data, combination data with PV-10 and systemic immunomodulatory agents in particular, and clinical mechanism of action data for both PV-10 and PH-10.

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 are discussing transactions with potential partners in China, India, Brazil and in other geographies.

We also recently announced discussions continuing with Sinopharm-China State Institute of Pharmaceutical Industry (Sinopharm-CSIPI), the leader among all pharmaceutical research institutes in China, and Sinopharm A-THINK Pharmaceutical Co., Ltd. (Sinopharm A-THINK), the only injectable anti-tumor drug research and development, manufacture and distribution integrated platform within Sinopharm Group. The discussions are based on the frame of reference established in the original Memorandum of Understanding (MOU) signed last year and extended since the passing of the original deadline. The original MOU was signed in August 2014, and, since then, the parties have sought to enter into a definitive licensing agreement, subject to additional negotiation, due diligence, and any required regulatory and corporate approvals.

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 systemic immunomodulatory agents, immune checkpoint inhibitors or systemic immunotherapies. Our recently announced joint patent issuance co-owned with Pfizer supports these efforts from an intellectual property protection perspective.

If and when we obtain an MOU, definitive agreement or similar indication of interest from a potential partner, we will issue a press release and file a Current Report on Form 8-K with the Securities and Exchange Commission to notify the market. Furthermore, the strategy of the Company for the benefit of stockholders 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. An interim transaction could be a co-development deal like Roche-NewLink, Bristol-Celldex or AstraZeneca-Incyte. The Company is not in discussions regarding the sale of its business, and there can be no assurance that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

We have signed multiple advisory agreements with accomplished individuals and organizations to help identify partners, including collaborators, distribution and joint venture partners, and licensees for PV-10 in China, Brazil and Latin America in general, India, Russia, European Union (EU), Japan and North America. These agreements are intended to enhance our reach into key markets and will bolster our efforts in developing partnering opportunities in various countries in Asia including China, India, Russia and Japan, where we have held numerous detailed discussions with pharmaceutical companies over the last year, and now also in Brazil, Europe and elsewhere. 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 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 stockholders 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 should 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 known as ablative immunotherapy or oncolytic immunotherapy. The primary ablative mechanism of PV-10 is followed by a secondary immunomodulatory mechanism. Likewise, we believe our development of PH-10 with existing funds should 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 licensing either PV-10 or PH-10, entering into 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 2017 and beyond, even though we do not anticipate needing additional capital to develop PV-10 on our

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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 stockholders.

## **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 2014 Form 10-K.

## 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 \$0 as of September 30, 2015.

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

We had no holdings of financial or commodity instruments as of September 30, 2015, 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 6 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 September 30, 2015, 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.

## PART II OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS.

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

Kleba Shareholder Derivative Lawsuit

On January 2, 2013, Glenn Kleba, 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 alleged (i) breach of fiduciary duties, (ii) waste of corporate assets, and (iii) unjust enrichment, all three claims based on Mr. Kleba 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 Mr. Kleba 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 February 21, 2014, an Amended Shareholder Derivative Complaint was filed which added Don B. Dale (Mr. Dale) as a plaintiff.

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 Mr. Kleba, Mr. Dale 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. The payment to plaintiff s counsel was made by the Company during October 2014 and is still recorded as other current assets at September 30, 2015 and December 31, 2014. The Company is seeking reimbursement of the full amount from insurance and if the full amount is not received from insurance, the amount remaining will be reimbursed to the Company from the Individual Defendants.

On October 3, 2014, the Settlement was effective and stock options for Drs. Dees and Scott and Mr. Culpepper were rescinded, totaling 2,800,000. \$733,333 was repaid by the Executives as of September 30, 2015. The first year payment due has been paid. The remaining cash settlement amounts will continue to be repaid to the Company over a period of four years with the second payment due in total by October 2016 and the final payment is expected to be received by October 3, 2019. \$80,105 of the settlement discount was amortized as of September 30, 2015. The remaining balance due the Company as of September 30, 2015 is \$3,746,667 with a present value discount remaining of \$288,217.

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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) of the Company s melanoma drug, PV-10, in the Spring of 2014, and the FDA s subsequent denial of the Company s application for BTD.

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.

On November 26, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order appointing Fawwaz Hamati as the Lead Plaintiff in the Securities Litigation, with the Law Firm of Glancy Binkow & Goldberg, LLP as counsel to Lead Plaintiff. On February 3, 2015, the Court entered an order compelling the Lead Plaintiff to file a consolidated amended complaint within 60 days of entry of the order.

On April 6, 2015, the Lead Plaintiff filed a Consolidated Amended Class Action Complaint (the Consolidated Complaint) in the Class Action Case, alleging that Provectus and the other individual defendants made knowingly false representations about the likelihood that PV-10 would be approved as a candidate for BTD, and that such representations caused injury to Lead Plaintiff and other shareholders. The Consolidated Complaint also added Eric Wachter as a named defendant.

On June 5, 2015, Provectus filed its Motion to Dismiss the Consolidated Complaint (the Motion to Dismiss ). On July 20, 2015, the Lead Plaintiff filed his response in opposition to the Motion to Dismiss (the Response ). Pursuant to order of the Court, Provectus replied to the Response on September 18, 2015.

On October 1, 2015, the Court entered an order staying a ruling on the Motion to Dismiss pending a mediation to resolve the Securities Litigation in its entirety. A mediation occurred on October 28, 2015, and discussions are continuing.

If the mediation is unsuccessful at resolving the Securities Litigation, the Company intends to defend vigorously against all claims in the Consolidated Complaint. However, in view of the inherent uncertainties of litigation and the early stage of this litigation, the outcome of the Class Action Case cannot be predicted at this time. Likewise, the amount of any potential loss cannot be reasonably estimated. No amounts have been recorded in the consolidated financial statements as the outcome of the Class Action Case cannot be predicted and the amount of any potential loss is not estimable at this time.

Hurtado Shareholder Derivative Lawsuit

On June 4, 2014, Karla Hurtado, derivatively on behalf of the Company, filed a shareholder derivative complaint in the United States District Court for the Middle District of Tennessee 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 Ms. Hurtado s allegations that the Individual Defendants (a) recklessly permitted the Company to make false and misleading disclosures and (b) failed to implement adequate controls and procedures to ensure the accuracy of the Company's disclosures.

On July 25, 2014, the United States District Court for the Middle District of Tennessee entered an order transferring the case to the United States District Court for the Eastern District of Tennessee and, in light of the pending Securities Litigation, relieving the Individual Defendants from responding to the complaint in the Hurtado Shareholder Derivative Lawsuit pending further order from the United States District Court for the Eastern District of Tennessee. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado Shareholder Derivative Lawsuit pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

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

Montiminy Shareholder Derivative Lawsuit

On October 24, 2014, Paul Montiminy brought a shareholder derivative complaint on behalf of the Company in the United States District Court for the Eastern District of Tennessee (the Montiminy Shareholder Derivative Lawsuit ) against H. Craig Dees, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ). Like the Hurtado Shareholder Derivative Lawsuit, the Montiminy Shareholder Derivative Lawsuit alleges (i) breach of fiduciary duties and (ii) gross mismanagement of the assets and business of the Company, both claims based on Mr. Montiminy s allegations that the Individual Defendants recklessly permitted the Company to make certain false and misleading disclosures regarding the likelihood that the Company s melanoma drug, PV-10, would qualify for BTD. As a practical matter, the factual allegations and requested relief in the Montiminy Shareholder Derivative Lawsuit are substantively the same as those in the Hurtado Shareholder Derivative Lawsuit.

On December 29, 2014, the United States District Court for the Eastern District of Tennessee (the Court ) entered an order consolidating the Hurtado Shareholder Derivative Lawsuit and the Montiminy Derivative Lawsuit. On February 25, 2015, the parties submitted a proposed agreed order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits until the Court issues a ruling on the anticipated motion to dismiss the amended consolidated complaint to be filed in the Securities Litigation. On April 9, 2015, the United States District Court for the Eastern District of Tennessee entered an Order staying the Hurtado and Montiminy Shareholder Derivative Lawsuits pending a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As in the Hurtado Shareholder Derivative Lawsuit, no relief is sought against the Company itself; the action is against the Individual Defendants only.

Foley Shareholder Derivative Complaint

On October 28, 2014, Chris Foley, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee 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 Foley Shareholder Derivative Lawsuit). The Foley Shareholder Derivative Lawsuit was brought by the same attorney as the Montiminy Shareholder Derivative Lawsuit, Paul Kent Bramlett of Bramlett Law Offices. Other than the difference in the named plaintiff, the complaints in the Foley Shareholder Derivative Lawsuit and the Montiminy Shareholder Derivative Lawsuit are identical. On March 6, 2015, the Chancery Court of Knox County, Tennessee entered an Order staying the Foley Derivative Lawsuit until the United States District Court for the Eastern District of Tennessee issues a ruling on the Motion to Dismiss filed by Provectus in the Class Action Case.

As in the Hurtado and Montiminy Shareholder Derivative Lawsuits, no relief is sought against the Company itself; the action is against the Individual Defendants only.

Donato Shareholder Derivative Lawsuit

On June 24, 2015, Sean Donato, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Chancery Court of Knox County, Tennessee 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 Donato Shareholder Derivative Lawsuit). Other than the difference in the named plaintiff, the Donato Shareholder Derivative Lawsuit is virtually identical to the other pending derivative lawsuits. All of these cases assert claims against the Defendants for breach of fiduciary duties based on the Company s purportedly misleading statements about the likelihood that PV-10 would be approved by the FDA. We are not in a position at this time to give you an evaluation of the likelihood of an unfavorable outcome, or an estimate of the amount or range of potential loss to the Company.

#### 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, 2014.

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

During the three months ended March 31, 2015, the Company issued 3,000 warrants to consultants in exchange for services. During the three months ended June 30, 2015, the Company issued 100,000 warrants to consultants in exchange for services. During the three months ended September 30, 2015, the Company issued 79,500 warrants to consultants in exchange for services. The Company intends to use any net proceeds from the exercises of these warrants for working capital, FDA trials, securing licensing partnerships, and general corporate purposes.

During the three months ended March 31, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$776,000. The Company received subscriptions, in the aggregate, for 776,000 shares of common stock and five year warrants to purchase 388,000 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants is \$1.00. The Company plans to use the proceeds for working capital and other general corporate purposes. Network 1 Financial Securities, Inc. served as placement agent for the offering. In connection with the offering, the Company paid \$100,880 and issued five year fully vested warrants to purchase 77,600 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% of the total number of shares of common stock subscribed for by investors solicited by Network 1 Financial Securities, Inc.

During the three months ended June 30, 2015, the Company completed a private offering of common stock and warrants to accredited investors for gross proceeds of \$1,011,100. The Company accepted subscriptions, in the aggregate, for 1,011,100 shares of common stock and five year warrants to purchase 505,550 shares of common stock. Investors received five year fully vested warrants to purchase up to 50% of the number of shares purchased by the investors in the offering. The warrants have an exercise price of \$1.25 per share. The purchase price for each share of common stock together with the warrants was \$1.00. 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 \$131,443 and issued five year fully vested warrants to purchase 101,110 shares of common stock with an exercise price of \$1.25 to Network 1 Financial Securities, Inc., which represents 10% 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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## **ITEM 6. EXHIBITS**

# **Exhibit**

No.	Description
3.1**	Certificate of Incorporation, as amended.
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.

<sup>\*\*</sup> Filed herewith.

## **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.

November 5, 2015

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)

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