

PROVECTUS BIOPHARMACEUTICALS, INC.

Form 10-Q

August 09, 2016

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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, 2016**

.. **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)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>	<b>90-0031917</b>
<b>incorporation or organization)</b>	<b>(I.R.S. Employer</b>
<b>7327 Oak Ridge Highway, Suite A,</b>	<b>Identification No.)</b>
<b>Knoxville, Tennessee</b>	<b>37931</b>
<b>(Address of principal executive offices)</b>	<b>(Zip Code)</b>
<b>866-594-5999</b>	
<b>(Registrant's telephone number, including area code)</b>	

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 August 5, 2016 was 212,829,352.



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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, 2015), 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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## PROVECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2016 (Unaudited)	December 31, 2015
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 4,891,313	\$ 14,178,902
Short-term receivable - settlement	200,000	500,000
Other current assets	316,585	41,192
<b>Total Current Assets</b>	<b>5,407,898</b>	<b>14,720,094</b>
Equipment and furnishings, less accumulated depreciation of \$458,020 and \$451,028, respectively	78,153	85,145
Patents, net of amortization of \$9,138,417 and \$8,802,857, respectively	2,577,028	2,912,588
Long-term receivable reimbursable legal fees, net of reserve for uncollectibility	683,250	683,250
Long-term receivable settlement, net of discount	2,055,547	2,011,735
Other assets	27,000	27,000
<b>Total Assets</b>	<b>\$ 10,828,876</b>	<b>\$ 20,439,812</b>
<b>Liabilities and Stockholders Equity</b>		
<b>Current Liabilities</b>		
Accounts payable trade	\$ 773,093	\$ 1,887,171
Accrued consulting expense	192,000	133,282
Accrued settlement expense		1,850,000
Other accrued expenses	723,617	252,418
<b>Total Current Liabilities</b>	<b>1,688,710</b>	<b>4,122,871</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders Equity</b>		
Preferred stock; par value \$.001 per share; 25,000,000 shares authorized; no shares issued and outstanding, respectively		
Common stock; par value \$.001 per share; 400,000,000 shares authorized; 212,829,352 and 204,979,100 shares issued and outstanding, respectively	212,829	204,979
Additional paid-in capital	203,273,872	196,908,112
Accumulated deficit	(194,346,535)	(180,796,150)

Total Stockholders Equity	9,140,166	16,316,941
Total Liabilities and Stockholders Equity	\$ 10,828,876	\$ 20,439,812

See accompanying notes to condensed consolidated financial statements.

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## PROTECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	<b>Three Months Ended June 30, 2016</b>	<b>Three Months Ended June 30, 2015</b>	<b>Six Months Ended June 30, 2016</b>	<b>Six Months Ended June 30, 2015</b>
Operating expenses				
Research and development	\$ 2,004,962	\$ 2,224,623	\$ 4,412,946	\$ 4,673,109
General and administrative	3,039,874	2,367,041	9,139,106	4,539,026
Total operating loss	(5,044,836)	(4,591,664)	(13,552,052)	(9,212,135)
Investment income	754	1,147	1,667	2,485
Gain on change in fair value of warrant liability		45,568		139,594
Net loss	\$ (5,044,082)	\$ (4,544,949)	\$ (13,550,385)	\$ (9,070,056)
Basic and diluted loss per common share	\$ (0.02)	\$ (0.02)	\$ (0.06)	\$ (0.05)
Weighted average number of common shares outstanding basic and diluted	212,829,352	187,792,643	209,053,930	186,501,656

See accompanying notes to condensed consolidated financial statements.



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## PROVECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	<b>Six Months Ended June 30, 2016</b>	<b>Six Months Ended June 30, 2015</b>
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (13,550,385)	\$ (9,070,056)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	6,992	6,378
Amortization of patents	335,560	335,560
Warrant incentive expense	2,718,407	
Issuance of stock for services	20,163	127,000
Issuance of warrants for services		55,214
Gain on change in fair value of warrant liability		(139,594)
(Increase) decrease in assets		
Settlement receivable	256,188	533,333
Other current assets	(275,393)	(207,801)
Increase (decrease) in liabilities		
Accounts payable	(1,114,078)	77,836
Accrued settlement expense	(1,850,000)	
Accrued expenses	529,917	62,918
<b>Net cash used in operating activities</b>	<b>(12,922,629)</b>	<b>(8,219,212)</b>
<b>Cash Flows From Financing Activities</b>		
Net proceeds from sales of common stock and warrants		13,653,927
Net proceeds from the issuance of common stock and warrants pursuant to warrant exchange offer	3,635,040	
Proceeds from exercises of warrants and stock options		290,828
<b>Net cash provided by financing activities</b>	<b>3,635,040</b>	<b>13,944,755</b>
<b>Net change in cash and cash equivalents</b>	<b>\$ (9,287,589)</b>	<b>\$ 5,725,543</b>
Cash and cash equivalents, at beginning of period	14,178,902	17,391,601
<b>Cash and cash equivalents, at end of period</b>	<b>\$ 4,891,313</b>	<b>\$ 23,117,144</b>
Interest and Taxes:	\$	\$

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 ( GAAP ) for interim financial information pursuant to Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

**2. Liquidity and Financial Condition**

The Company's cash and cash equivalents were \$4,891,313 at June 30, 2016, compared with \$14,178,902 at December 31, 2015. The Company continues to incur significant operating losses and management expects that significant on-going operating expenditures will be necessary to successfully implement the Company's business plan and develop and market its products. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. Implementation of the Company's plans and its ability to continue as a going concern will depend upon the Company's ability to develop PV-10 and raise additional capital.

Management believes that the Company has access to capital resources through possible public or private equity offerings, exchange offers, debt financings, corporate collaborations or other means. In addition, the Company continues to explore opportunities to strategically monetize its lead drug candidate, PV-10, through potential licensing transactions, although there can be no assurance that the Company will be successful with such plans. The Company has historically been able to raise capital through equity offerings, although no assurance can be provided that it will continue to be successful in the future. If the Company is unable to raise sufficient capital, it may be forced to implement significant cost cutting measures as early as the third quarter of 2016.

**3. Nature of Operations and Significant Accounting Policies**

**Nature of Operations**

Provectus Biopharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, the Company ), is a biopharmaceutical company that 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 not generated any 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 prescription drug candidates, or sell or license the Company's over-the-counter ( OTC ) products or non-core technologies.

**Principles of Consolidation**

Intercompany balances and transactions have been eliminated in consolidation.

**Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: amortization of patents, payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, legal, insurance, rent and utilities, and depreciation.

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In February 2016, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2016-02, Leases ( ASU 2016-02 ), which amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective beginning in the first quarter of 2019. Early adoption of ASU 2016-02 is permitted. The new standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on our condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*. This ASU amends the principal versus agent guidance in ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which was issued in May 2014 ( ASU 2014-09 ). Further, in April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*. This ASU also amends ASU 2014-09 and is related to the identification of performance obligations and accounting for licenses. The effective date and transition requirements for both of these amendments to ASU 2014-09 are the same as those of ASU 2014-09, which was deferred for one year by ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*. That is, the guidance under these standards is to be applied using a full retrospective method or a modified retrospective method, as outlined in the guidance, and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted only for annual periods, and interim period within those annual periods, beginning after December 15, 2016. The Company is currently evaluating the provisions of each of these standards and assessing their impact on the Company's condensed consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This ASU makes targeted amendments to the accounting for employee share-based payments. This guidance is to be applied using various transition methods such as full retrospective, modified retrospective, and prospective based on the criteria for the specific amendments as outlined in the guidance. The guidance is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2016. Early adoption is permitted, as long as all of the amendments are adopted in the same period. The Company is currently evaluating the provisions of this guidance and assessing its impact on the Company's condensed consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-03, *Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments*, which clarifies the requirements for assessing whether contingent call or put options that can accelerate the repayment of principal on debt instruments are clearly and closely related to their debt hosts. This guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within those annual reporting periods, and early adoption is permitted. The Company is currently evaluating the provisions of this guidance and assessing its impact on the Company's condensed consolidated financial statements and disclosures.

**Basic and Diluted Loss Per Common Share**

Basic loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the incremental common shares issuable upon the exercise of warrants and stock options (using the treasury stock

method). Diluted loss per share excludes the shares issuable upon the conversion of the exercise of stock options and warrants from the calculation of net loss per share as their effect would be anti-dilutive. Loss per share excludes the impact of outstanding options and warrants as they are antidilutive. Potential common shares excluded from the calculation at June 30, 2016 and 2015, respectively, relate to 77,874,686 and 79,680,528 from warrants, and 6,800,000 and 9,545,214 from options.

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

(a) During the three months ended March 31, 2016, the Company issued 51,745 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$20,163. 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 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.

(b) During the three months ended March 31, 2016, 1,048,494 warrants expired. 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 expired.

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During the three months ended June 30, 2016, 1,757,253 warrants expired. During the three months ended June 30, 2016, employees of the Company forfeited 3,830,000 stock options. During the three months ended June 30, 2015, the Company issued 100,000 fully vested warrants to consultants in exchange for services, and charged to consulting costs \$53,582. During the three months ended June 30, 2015, 1,161,790 warrants expired.

(c) As of December 28, 2015, the Company had outstanding warrants to purchase an aggregate of 59,861,601 shares of common stock, which were issued between January 6, 2011 and November 1, 2015 in transactions exempt from registration under the Securities Act (the Existing Warrants ). Each Existing Warrant has an exercise price of between \$1.00 and \$3.00 per share, and expires between January 6, 2016 and November 1, 2020. On December 31, 2015, the Company offered pursuant to an Offer Letter/Prospectus 59,861,601 shares of its common stock for issuance upon exercise of the Existing Warrants. The shares issued upon exercise of the Existing Warrants are unrestricted and freely transferable. The Offer was to temporarily modify the terms of the Existing Warrants so that each holder who tendered Existing Warrants during the Offer Period for early exercise were able to do so at a discounted exercise price of \$0.50 per share. Each Existing Warrant holder who tendered Existing Warrants for early exercise during the Offer Period received, in addition to the shares of Common Stock purchased upon exercise, an equal number of new warrants to purchase common stock, with an exercise price of \$0.85 per share, expiring June 19, 2020 (the Replacement Warrants ). The modification of the exercise price of the Existing Warrants and the Replacement Warrants are treated as an inducement to enter into the exchange offer and were accounted for as of the closing date. The exchange offer expired at 4:00 p.m., Eastern Time, on March 28, 2016. The Company accepted for purchase approximately 7,798,507 Existing Warrants properly tendered, resulting in the issuance of approximately 7,798,507 shares of common stock upon exercise of Existing Warrants and the issuance of approximately 7,798,507 Replacement Warrants, resulting in gross proceeds of \$3,899,254 upon closing of the exchange offer. Maxim Group LLC and Network 1 Financial Securities, Inc. received a total of \$264,214 in placement agent fees and 467,910 warrants with a cash exercise price of \$0.85 per share which expire on June 19, 2020, unless sooner exercised. In connection with the exchange offer, a warrant incentive expense totaling \$2,718,407 was recorded. The value was determined using the Black-Scholes option-pricing model between the Existing Warrants exchanged and the common stock and Replacement Warrants received.

On May 13, 2016, the Company offered pursuant to an Offer Letter/Prospectus 51,149,594 shares of its common stock for issuance upon exercise of the Existing Warrants. The Offer was to temporarily modify the terms of the Existing Warrants so that each holder who tendered Existing Warrants during the Offer Period for early exercise were able to do so at a discounted exercise price of \$0.75 per share. Each Existing Warrant holder who tendered Existing Warrants for early exercise during the Offer Period were to receive, in addition to the shares of Common Stock purchased upon exercise, an equal number of new warrants to purchase common stock, with an exercise price of \$0.85 per share, expiring June 19, 2020 (the Replacement Warrants ). The exchange offer expired at 4:00 p.m., Eastern Time, on July 28, 2016 with no warrants tendered.

## 5. Related Party Transactions

Under the terms of the Amended and Restated Executive Employment Agreement entered into by Dr. H. Craig Dees, the Company's former Chairman and Chief Executive Officer ( Former CEO ) and the Company on April 28, 2014 (the Agreement ), the Former CEO is owed no severance payments as a result of his resignation on February 27, 2016. The Former CEO's employment terminated with his resignation without Good Reason as that term is defined in the Agreement. Under section 6 of the Agreement, Effect of Termination, a resignation by the Former CEO without Good Reason terminates any payments due to the Former CEO as of the last day of his employment. As reported in the Company's press release furnished with the Company's Current Report on Form 8-K filed with the Commission on February 29, 2016, in connection with the resignation of the Former CEO as the Company's Chief Executive Officer and Chairman of the Board of Directors, which was effective February 27, 2016, the Audit Committee conducted a

review of Company procedures, policies and practices, including travel expense advancements and reimbursements. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. On March 15, 2016, the Audit Committee completed this investigation and made the following findings: (1) in 2015, the Former CEO received \$898,430 in travel expense advances but submitted receipts totaling only \$297,170, most of which did not appear to be authentic; (2) in 2014, the Former CEO received \$819,000 for travel expense advances, for which no receipts were submitted; and (3) in 2013, the Former CEO received \$752,034 for travel expense advances; no receipts were submitted by the Former CEO for \$698,000 of these expenses and \$54,034 of submitted receipts did not appear to be authentic. In addition, the Company advanced travel expenses to the Former CEO in the amount of \$56,627 in the first quarter of 2016 prior to his resignation and prior to the completion of the Company's investigation. The Company has filed a lawsuit in the United States District Court for the Eastern District of Tennessee seeking to collect all of the Former CEO's unsubstantiated travel expenses, including those which did not appear to be authentic. See Note 6, *Litigation - Collection Lawsuit*.

## **6. 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 the Former CEO, Timothy C. Scott, Eric A. Wachter, and Peter R.



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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 the Former CEO 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. At that time, the Company 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 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 was recorded as other current assets at December 31, 2014, as the Company is seeking reimbursement of the full amount from its insurance carrier. If the full amount is not received from insurance, the amount remaining will be reimbursed to the Company.

from the Individual Defendants. The amount was reclassified to long-term receivable at December 31, 2015 and is recorded as long-term receivable at June 30, 2016. A reserve for uncollectibility of \$227,750 was established at December 31, 2015 in connection with the resignation of the Former CEO. As of June 30, 2016, the Company has the net amount of the receivable of \$683,250 included in long term assets on its condensed balance sheet.

On October 3, 2014, the Settlement was effective and stock options for the Former CEO, Dr. Scott and Mr. Culpepper were rescinded, totaling 2,800,000. \$900,000 was repaid by the Executives as of December 31, 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. \$150,000 was repaid by the Executives during the three months ended June 30, 2016, and a total of \$300,000 was repaid for the six months ended June 30, 2016. An additional \$21,258 of the settlement discount was amortized as of June 30, 2016, and a total of \$43,812 was amortized for the six months ended June 30, 2016. \$147,781 of the settlement discount was amortized as of June 30, 2016. The remaining balance due the Company as of June 30, 2016 is \$2,255,547, including a reserve for uncollectibility of \$870,578 in connection with the resignation of the Former CEO, with a present value discount remaining of \$153,874. As a result of his resignation, the Former CEO is no longer entitled to the 2:1 credit, such that his total repayment obligation of \$2,040,000 (the total \$2.24 million owed by the Former CEO pursuant to the Settlement less the \$200,000 that he repaid as of December 31, 2015) plus the Former CEO's proportionate share of the litigation costs is immediately due and payable. The Company sent the Former CEO a notice of default in March 2016 for the total amount he owes the Company.

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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, the Former CEO, 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 and seeking monetary damages. 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 Securities Litigation, 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. On January 28, 2016, a settlement terms sheet (the Terms Sheet ) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Securities Litigation.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Securities Litigation, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier agreed to pay the total amount of \$3.5 million (the Settlement Funds ) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Securities Litigation. The Company has determined that it is probable that the Company will pay \$1.85 million of the total, which has been accrued at December 31, 2015 and was paid in March 2016. The insurance carrier will pay \$1.65

million of the total directly to the plaintiff's trust escrow account. Notice will be provided to shareholder members of the class. Shareholder members of the class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Securities Litigation will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Securities Litigation and the Securities Litigation will be fully concluded. If the court does not give final approval of the settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the settlement and procedures for preliminary and final court approval was filed on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the Terms Sheet and includes the procedures for providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement further provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Securities Litigation.

On April 7, 2016, the court in the Securities Litigation held a hearing on preliminary approval of the settlement, entered an order preliminarily approving the settlement, ordered that the class be notified of the settlement as set forth in the Stipulation of Settlement, and set a hearing on September 26, 2016 to determine whether the proposed settlement is fair, reasonable, and adequate to the class; whether the class should be certified and the plan of allocation of the Settlement Funds approved; whether to grant Lead Plaintiff's request for expenses and Lead Plaintiff's counsel's request for fees and expenses; and whether to enter judgment dismissing the Securities Litigation as provided in the Stipulation of Settlement. If the settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.

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*2014-2015 Derivative Lawsuits*

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 the Former CEO, 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 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 the Former CEO, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants ). 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 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 the Company in the Securities Litigation.

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 the Former CEO, 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 the Company in the Securities Litigation.

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 the Former CEO, 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.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

While the parties to the Securities Litigation were negotiating and documenting the Stipulation of Settlement in the Securities Litigation, the parties to the Hurtado, Montiminy, and Foley Shareholder Derivative Lawsuits, through counsel, engaged in settlement negotiations as well. On or about April 11, 2016, the parties entered into a Stipulation of Settlement, which was filed with the United States District Court for the Eastern District of Tennessee on April 29, 2016.

Pursuant to the Stipulation of Settlement, the parties agreed to settle the cases, contingent upon the approval of the court. The Company agreed to implement certain corporate governance changes, including the adoption of a Disclosure Controls and Procedures Policy, and to use its best efforts to replace one of its existing directors with an independent outside director by June 30, 2017. The Company agreed to pay from insurance proceeds the amount of \$300,000 to plaintiffs' counsel in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits. The insurance carrier will pay directly to the plaintiff's trust escrow account and it will not pass through the Company. Notice of the proposed settlement will be provided to shareholders as set forth in the Stipulation of Settlement. If the court enters final approval of the settlement, the Individual Defendants will be released from any and all claims in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

The United States District Court for the Eastern District of Tennessee preliminarily approved the settlement by order dated June 2, 2016. Pursuant to this court order, the notice to the class was filed with the Securities and Exchange Commission, published on the Company's website, and posted on plaintiffs' counsel's websites by June 13, 2016. The Court set a final hearing on the fairness of the settlement to take place on August 26, 2016.

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*Collection Lawsuit*

On May 5, 2016, the Company filed a lawsuit in the United States District Court for the Eastern District of Tennessee at Knoxville against the Former CEO and his wife together with the Former CEO, the Defendants ). The Company alleges that between 2013 and the present, the Former CEO received approximately \$2.4 million in advanced or reimbursed travel and entertainment expenses from the Company and that the Former CEO did not use these funds for legitimate travel and entertainment expenses as he requested and the Company intended. Instead, the Company believes that the Former CEO created false receipts and documentation for the expenses and applied the funds to personal use. The Company and the Former CEO are parties to a Stipulated Settlement Agreement dated October 3, 2014 (the Kleba Settlement Agreement ) that was negotiated to resolve certain claims asserted against the Former CEO derivatively. Pursuant to the terms of the Kleba Settlement Agreement, the Former CEO agreed to repay the Company compensation that was paid to him along with legal fees and other expenses incurred by the Company. As of the date of his resignation, the Former CEO still owed the Company \$2,267,750 under the Kleba Settlement Agreement. The Former CEO has failed to make such payment, and the Company has notified him that he is in default and demanded payment in full. Therefore, the Company is alleging counts of conversion, fraud, breach of fiduciary duty, breach of contract, breach of Kleba Settlement Agreement, unjust enrichment and punitive damages in this lawsuit. The Company is seeking that the Defendants be prohibited from disposing of any property that may have been paid for with the misappropriated funds, the Defendants be disgorged of any funds shown to be fraudulently misappropriated and that the Company be awarded compensatory damages in an amount not less than \$5 million. Furthermore, we are seeking for the damages to be joint and several as to the Defendants and that punitive damages be awarded against the Former CEO in our favor.

*Other Regulatory Matters*

From time to time the Company receives subpoenas and/or requests for information from governmental agencies with respect to our business. The Company has received a subpoena from the staff of the Securities and Exchange Commission related to the travel expense advancements and reimbursements received by our Former CEO. At this time, the staff's investigation into this matter remains ongoing. The Company is cooperating with the staff but cannot predict with any certainty what the outcome of the foregoing may be.

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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, 2015 ( 2015 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 pharmaceutical products and continued execution of research programs for new research initiatives.

Peter R. Culpepper has agreed to serve as our Interim Chief Executive Officer until our Board of Directors completes its search process for a successor Chief Executive Officer to replace our Former CEO, who resigned effective February 27, 2016 as our Chief Executive Officer and Chairman of the Board of Directors. Our Board of Directors has also recently retained John R. Glass as our Interim Chief Financial Officer. We also plan to continue operating with our four primary consultants and various vendor relationships totaling sixty (60) full-time equivalents, and anticipate adding additional personnel or contract research organizations if necessary in the next 12 months. Our current plans also include minimal purchases of new property, plant and equipment, and increased research and development for additional clinical trials.

We believe that our investigational drugs PV-10 and PH-10 provide us with two products in multiple indications, which have been shown in clinical trials to be safe to treat serious cancers and diseases of the skin, and important immunologic data has been corroborated and characterized by institutions such as Moffitt Cancer Center in Tampa, Florida, M.D. Anderson in Houston, Texas, and the University of Illinois at Chicago. 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 result in one or more license transactions with pharmaceutical and or biotech companies. 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, 2016 and June 30, 2015**

###### *Revenues*

We had no revenue during the three and six months ended June 30, 2016 and 2015.

###### *Research and Development*

Research and development costs of \$2,004,962 for the three months ended June 30, 2016 included patent amortization expense of \$167,780, payroll of \$214,088, consulting and contract labor of \$1,451,745, legal of \$64,455, insurance of \$57,532, lab supplies and pharmaceutical preparations of \$21,876, rent and utilities of \$23,990, and depreciation expense of \$3,496. Research and development costs of \$2,224,623 for the three months ended June 30, 2015 included



patent amortization expense of \$167,780, payroll of \$408,440, consulting and contract labor of \$1,086,196, legal of \$177,686, insurance of \$30,833, lab supplies and pharmaceutical preparations of \$328,408, rent and utilities of \$22,091, and depreciation expense of \$3,189. The overall decrease in research and development costs is due primarily to a decrease of approximately \$200,000 in payroll due to the resignation of our Former CEO. The other research and development costs in total are consistent in the three months ended June 30, 2016 and 2015 due to the ongoing phase 3 study of PV-10 in locally advanced cutaneous melanoma, the phase 1b/2 combination study of PV-10 and Merck's KEYTRUDA in late stage melanoma, and the preparation of the phase 1b/2 study of PV-10 in liver cancer.

Research and development costs of \$4,412,946 for the six months ended June 30, 2016 included patent amortization expense of \$335,560, payroll of \$531,141, consulting and contract labor of \$3,187,874, legal of \$146,410, insurance of \$111,795, lab supplies and pharmaceutical preparations of \$39,743, rent and utilities of \$53,431, and depreciation expense of \$6,992. Research and development costs of \$4,673,109 for the six months ended June 30, 2015 included patent amortization expense of \$335,560, payroll of \$829,349, consulting and contract labor of \$2,603,845, legal of \$210,959, insurance of \$66,834, lab supplies and pharmaceutical preparations of \$578,804, rent and utilities of \$41,380, and depreciation expense of \$6,378. The overall decrease in research and development costs is due primarily to a decrease of approximately \$300,000 in payroll due to the resignation of our Former CEO. The other research and development costs in total are consistent in the six months ended June 30, 2016 and 2015 due to the ongoing phase 3 study of PV-10 in locally advanced cutaneous melanoma, the phase 1b/2 combination study of PV-10 and Merck's KEYTRUDA in late stage melanoma, and the preparation of the phase 1b/2 study of PV-10 in liver cancer.

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### *General and Administrative*

General and administrative expenses increased by \$672,833 in the three months ended June 30, 2016 to \$3,039,874 from \$2,367,041 for the three months ended June 30, 2015. General and administrative expenses were very similar for both periods except for two primary accounts. Approximately \$200,000 in increased expense is due to higher total of investor and public relations expense during the three months ended June 30, 2016 versus the three months ended June 30, 2015 due primarily to efforts to maximize the visibility and awareness of the Company in the marketplace. Approximately \$400,000 in increased expense is due to legal compliance during the three months ended June 30, 2016 versus the three months ended June 30, 2015 due primarily to increased legal costs associated with the audit committee's investigation into Company procedures, policies and practices, including travel expense advancements and reimbursements received by our Former CEO, offset by savings in payroll and travel related expenses due to the resignation of our Former CEO.

General and administrative expenses increased by \$4,600,080 in the six months ended June 30, 2016 to \$9,139,106 from \$4,539,026 for the six months ended June 30, 2015. General and administrative expenses were very similar for both periods except for three primary accounts. Approximately \$2.7 million in increased expense is due to the warrant incentive expense during the six months ended June 30, 2016 versus the six months ended June 30, 2015, as described in Note 4(c) to the accompanying financial statements. Approximately \$1.2 million in increased expense is due to higher total of investor and public relations expense during the six months ended June 30, 2016 versus the six months ended June 30, 2015 due primarily to efforts to maximize the warrant exchange transaction described in Note 4(c) to the accompanying financial statements. Approximately \$600,000 in increased expense is due to legal compliance during the six months ended June 30, 2016 versus the six months ended June 30, 2015 due primarily to increased legal costs associated with the audit committee's investigation into Company procedures, policies and practices, including travel expense advancements and reimbursements received by H. Craig Dees, our former Chairman and Chief Executive Officer, offset by savings in payroll and travel related expenses due to the resignation of our Former CEO.

### *Investment Income*

Investment income was insignificant in both the three and six months ended June 30, 2016 and 2015.

### *Gain/Loss on Change in Fair Value of Warrant Liability*

The change in fair value of warrant liability decreased by \$45,568 in the three months ended June 30, 2016 to \$0 from a gain of \$45,568 for the three months ended June 30, 2015.

The change in fair value of warrant liability decreased by \$139,594 in the six months ended June 30, 2016 to \$0 from a gain of \$139,594 for the six months ended June 30, 2015.

## **Liquidity and Capital Resources**

The Company's cash and cash equivalents were \$4,891,313 at June 30, 2016, compared with \$14,178,902 at December 31, 2015. The accompanying financial statements for the six months ended June 30, 2016 have been prepared on a basis that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of \$203 million as of June 30, 2016. These conditions raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to obtain additional financing as may be

required to fund current operations. Management's plans include selling its equity securities and obtaining other financing to fund its capital requirement and on-going operations; however, there can be no assurance the Company will be successful in these efforts. The financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern. Significant funds will be needed for the Company to continue and complete its Phase 3 clinical trials.

Management believes that the Company has access to capital resources through possible public or private equity offerings, exchange offers, debt financings, corporate collaborations or other means. 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. In addition, the Company continues to explore opportunities to strategically monetize its lead drug candidate, PV-10, through potential licensing transactions, although there can be no assurance provided that the Company will be successful with such plans. The Company has historically been able to raise capital through equity offerings, although no assurance can be provided that it will continue to be successful in the future. If the Company is unable to raise sufficient capital, it may be forced to implement significant cost cutting measures as early as the third quarter of 2016.

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We continue to provide 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 Russia.

We also announced throughout 2015 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 in 2014 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.

Also we announced in July 2015 signing a Letter of Intent (the LOI ) with Boehringer Ingelheim (China) Investment Co. Ltd. ( Boehringer ). The purpose of the LOI is to lay a foundation for the two parties to collaborate in bringing PV-10 to market in mainland China, Hong Kong and Taiwan. Maxim Group LLC acted as strategic advisor to Provectus in structuring and negotiating the LOI. Under the terms of the LOI, Boehringer will provide certain commercially reasonable support in the aspects of product registration with the China Food and Drug Administration ( CFDA ), communication preparation, market intelligence and other assistance to the Company in China to the extent that is within Boehringer s approved business scope and permissible by Chinese laws.

In return, we will grant Boehringer the first priority to be the exclusive collaborator of the Company in China for PV-10 in the event that PV-10 is successfully registered and approved by the CFDA. The exclusive collaboration may take the form of exclusive distribution and promotion, exclusive licensing or other agreement, subject to both parties mutual agreement. At the appropriate time, the Company and Boehringer may enter into a definitive agreement, including a non-compete provision, for PV-10 to be exclusively developed, distributed and promoted through the collaboration within China, although there can be no assurance that the parties will enter into a definitive agreement.

In the LOI signed July 2, 2015, at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer 2015 in Barcelona, the two parties have agreed to meet regularly and maintain effective communication in order to move forward with the registration and commercialization of the product and assess the potential cooperation between them in China, which may be adopted in a form of exclusive commercial supply, distribution and promotion, partnership or any other forms suitable to both parties interests.

We also have considered co-development transactions since 2015 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 announced joint patent issuance in 2015 co-owned with Pfizer supports these efforts from an intellectual property protection perspective. And our initiated phase 1b/2 study in September 2015 combining PV-10 and Merck s KEYTRUDA, a systemic immunotherapy also known as pembrolizumab, potentially demonstrates the relevance of PV-10 synergy with agents such as KEYTRUDA.

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 SEC 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 and the Indian Subcontinent, MENAT, 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.

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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 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 condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed 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 2015 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 \$30,000 as of June 30, 2016.

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

We had no holdings of financial or commodity instruments as of June 30, 2016, 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 were remeasured at each period end with the change in fair value recorded in the statement of operations. All such warrants were valued at \$0 as of December 31, 2015.

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. The formation of our Australian subsidiary is initially for the purpose of enabling lower clinical development costs in Australia and will not impact our financial statements.

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

(a) Evaluation of Disclosure Controls and Procedures. Our interim chief executive officer and interim 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, 2016, the end of the fiscal quarter covered

by this Quarterly Report on Form 10-Q. Based on that evaluation, the interim chief executive officer and interim chief financial officer have concluded that our disclosure controls and procedures are not 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.

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

Management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act at December 31, 2015. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures along with the related internal controls over financial reporting were not effective to provide reasonable assurance that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Such material weaknesses continued to exist at June 30, 2016.

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### ***Material Weakness***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Management's assessment of internal controls at December 31, 2015 identified the below-described material weakness.

Our internal control testing identified inadequate supporting documentation and lack of adequate review for travel advances and expense reimbursements.

The Audit Committee conducted a review of Company procedures, policies and practices, including travel expense advancements and reimbursements to our Former CEO. The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. As part of the investigation, the Committee reviewed our financial policies and procedures, including management expenses. The Audit Committee concluded that our Former CEO did not produce receipts for most of the travel expense advances he received from 2013 to 2015, and some receipts produced by our Former CEO during this period appear to have been altered.

We have identified the following material weakness related to our travel expense advancement and reimbursement policies and procedures to our Former CEO: (1) the documentation provided for an expenditure was not sufficient to support the authorization of such expenditure, (2) only the check register and not the supporting documentation was obtained by an executive officer approving the expenses incurred by another executive officer, and (3) there was no reconciliation of travel advances to actual expenses.

### **Inherent Limitations on Effectiveness of Controls**

Even assuming the effectiveness of our controls and procedures, our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error or all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. In general, our controls and procedures are designed to provide reasonable assurance that our control system's objective will be met, and our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures are not effective at the reasonable assurance level. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls in future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of



our financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures by us are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

***Remediation***

We continue to aggressively remediate the material weakness in our internal controls over financial reporting. To do so, we have put in place more clearly defined, tighter controls, including a clear process for limiting, approving and documenting travel advances and expenses and appropriately managing them. Specifically, we have:

Adopted a control enhancement to require the provision of all invoice copies along with the check register for appropriate approval, including all travel reimbursements separately approved;

Established a policy so travel advances are no longer permitted; and

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Implemented a more formal and detailed travel and expense policy. In addition, we have replaced the independent consulting group previously utilized by management to aid in our documentation and testing of internal controls over financial reporting and appointed John Glass as our Interim Chief Financial Officer to assist in the organization and strategic operation of the Company as to its procedures and daily operations of the Company. We are also in the process of implementing many of the other recommendations made by counsel to the Audit Committee to remediate these issues, including the identification and recruitment of a permanent Chief Executive Officer and any other positions necessary. We believe the foregoing actions will continue to improve our internal control over financial reporting as well as our disclosure controls and procedures. We will continue to monitor the effectiveness of our internal control over financial reporting in the area affected by the material weakness discussed above, and will perform any additional procedures, as well as implement any new resources and policies, deemed necessary by our management to remediate the material weakness.

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**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 Former CEO, 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. At that time, the Company 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 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 was recorded as other current assets at December 31, 2014, as the Company is seeking reimbursement of the full amount from its insurance carrier. If the full amount is not received from insurance, the amount remaining will be reimbursed to the Company from the Individual Defendants. The amount was reclassified to long-term receivable at December 31, 2015. A reserve for uncollectibility of \$227,750 was established at December 31, 2015 in connection with the resignation of the Former CEO. As of June 30, 2016, the Company has the net amount of the receivable of \$683,250 included in long term assets on its condensed balance sheet.

On October 3, 2014, the Settlement was effective and stock options for the Former CEO, Dr. Scott and Mr. Culpepper were rescinded, totaling 2,800,000. \$900,000 was repaid by the Executives as of December 31, 2015. The first year payment due has been paid. The

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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. \$150,000 was repaid by the Executives during the three months ended June 30, 2016, and a total of \$300,000 was repaid for the six months ended June 30, 2016. An additional \$21,258 of the settlement discount was amortized as of June 30, 2016, and a total of \$43,812 was amortized for the six months ended June 30, 2016. \$147,781 of the settlement discount was amortized as of June 30, 2016. The remaining balance due the Company as of June 30, 2016 is \$2,255,547, including a reserve for uncollectibility of \$870,578 in connection with the resignation of the Former CEO, with a present value discount remaining of \$153,874. As a result of his resignation, the Former CEO is no longer entitled to the 2:1 credit, such that his total repayment obligation of \$2,040,000 (the total \$2.24 million owed by the Former CEO pursuant to the Settlement less the \$200,000 that he repaid as of December 31, 2015) plus the Former CEO's proportionate share of the litigation costs is immediately due and payable. The Company sent the Former CEO a notice of default in March 2016 for the total amount he owes the Company.

*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, the Former CEO, 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 and seeking monetary damages. 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 Securities Litigation, 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. On January 28, 2016, a settlement terms sheet (the Terms Sheet ) was executed by counsel for the Company and counsel for the Lead Plaintiff in the consolidated Securities Litigation.

Pursuant to the Terms Sheet, the parties agree, contingent upon the approval of the court in the consolidated Securities Litigation, that the cases will be settled as a class action on the basis of a class period of December 17, 2013 through May 22, 2014. The Company and its insurance carrier agreed to pay the total amount of \$3.5 million (the Settlement Funds ) into an interest bearing escrow account upon preliminary approval by the court in the Consolidated Securities Litigation. The Company has determined that it is probable that the Company will pay \$1.85 million of the total, which has been accrued at December 31, 2015 and was paid in March 2016. The insurance carrier will pay \$1.65 million of the total directly to the plaintiff s trust escrow account and it will not pass through the Company. Notice will be provided to shareholder members of the class. Shareholder members of the class will have both the opportunity to file claims to the Settlement Funds and to object to the settlement. If the court enters final approval of the settlement, the Securities Litigation will be dismissed with full prejudice, the Defendants will be released from any and all claims in the Securities Litigation and the Securities Litigation will be fully concluded. If the court does not give final approval of the settlement, the Settlement Funds, less any claims administration expenses, will be returned to the Company and its insurance carrier.

A Stipulation of Settlement encompassing the details of the settlement and procedures for preliminary and final court approval was filed on March 8, 2016. The Stipulation of Settlement incorporates the provisions of the Terms Sheet and includes the procedures for

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providing notice to stockholders who bought or sold stock of the Company during the class period. The Stipulation of Settlement further provides for (1) the methodology of administering and calculating claims, final awards to stockholders, and supervision and distribution of the Settlement Funds and (2) the procedure for preliminary and final approval of the settlement of the Securities Litigation.

On April 7, 2016, the court in the Securities Litigation held a hearing on preliminary approval of the settlement, entered an order preliminarily approving the settlement, ordered that the class be notified of the settlement as set forth in the Stipulation of Settlement, and set a hearing on September 26, 2016 to determine whether the proposed settlement is fair, reasonable, and adequate to the class; whether the class should be certified and the plan of allocation of the Settlement Funds approved; whether to grant Lead Plaintiff's request for expenses and Lead Plaintiff's counsel's request for fees and expenses; and whether to enter judgment dismissing the Securities Litigation as provided in the Stipulation of Settlement. If the settlement is not approved and consummated, the Company intends to defend vigorously against all claims in the Consolidated Complaint.

*2014-2015 Derivative Lawsuits*

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 the Former CEO, 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 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 the Former CEO, Timothy C. Scott, Jan E. Koe, Kelly M. McMasters, and Alfred E. Smith, IV (collectively, the Individual Defendants). 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 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 the Company in the Securities Litigation.

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 the Former CEO, 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 the Company in the Securities Litigation.

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 the Former CEO, 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.

As a nominal defendant, no relief is sought against the Company itself in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

While the parties to the Securities Litigation were negotiating and documenting the Stipulation of Settlement in the Securities Litigation, the parties to the Hurtado, Montiminy, and Foley Shareholder Derivative Lawsuits, through counsel, engaged in settlement negotiations as well. On or about April 11, 2016, the parties entered into a Stipulation of Settlement, which was filed with the United States District Court for the Eastern District of Tennessee on April 29, 2016.



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Pursuant to the Stipulation of Settlement, the parties agreed to settle the cases, contingent upon the approval of the court. The Company agreed to implement certain corporate governance changes, including the adoption of a Disclosure Controls and Procedures Policy, and to use its best efforts to replace one of its existing directors with an independent outside director by June 30, 2017. The Company agreed to pay from insurance proceeds the amount of \$300,000 to plaintiffs' counsel in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits. The insurance carrier will pay directly to the plaintiff's trust escrow account and it will not pass through the Company. Notice of the proposed settlement will be provided to shareholders as set forth in the Stipulation of Settlement. If the court enters final approval of the settlement, the Individual Defendants will be released from any and all claims in the Hurtado, Montiminy, Foley, and Donato Shareholder Derivative Lawsuits.

The United States District Court for the Eastern District of Tennessee preliminarily approved the settlement by order dated June 2, 2016. Pursuant to this court order, the notice to the class was filed with the Securities and Exchange Commission, published on the Company's website, and posted on plaintiffs' counsel's websites by June 13, 2016. The Court set a final hearing on the fairness of the settlement to take place on August 26, 2016.

### *Collection Lawsuit*

On May 5, 2016, the Company filed a lawsuit in the United States District Court for the Eastern District of Tennessee at Knoxville against the Former CEO and his wife, and together with the Former CEO, the Defendants. The Company alleges that between 2013 and the present, the Former CEO received approximately \$2.4 million in advanced or reimbursed travel and entertainment expenses from the Company and that the Former CEO did not use these funds for legitimate travel and entertainment expenses as he requested and the Company intended. Instead, the Company believes that the Former CEO created false receipts and documentation for the expenses and applied the funds to personal use. The Company and the Former CEO are parties to a Stipulated Settlement Agreement dated October 3, 2014 (the Kleba Settlement Agreement) that was negotiated to resolve certain claims asserted against the Former CEO derivatively. Pursuant to the terms of the Kleba Settlement Agreement, the Former CEO agreed to repay the Company compensation that was paid to him along with legal fees and other expenses incurred by the Company. As of the date of his resignation, the Former CEO still owed the Company \$2,267,750 under the Kleba Settlement Agreement. The Former CEO has failed to make such payment, and the Company has notified him that he is in default and demanded payment in full. Therefore, the Company is alleging counts of conversion, fraud, breach of fiduciary duty, breach of contract, breach of Kleba Settlement Agreement, unjust enrichment and punitive damages in this lawsuit. We are seeking that the Defendants be prohibited from disposing of any property that may have been paid for with the misappropriated funds, the Defendants be disgorged of any funds shown to be fraudulently misappropriated and that the Company be awarded compensatory damages in an amount not less than \$5 million. Furthermore, we are seeking for the damages to be joint and several as to the Defendants and that punitive damages be awarded against the Former CEO in our favor.

### *Other Regulatory Matters*

From time to time the Company receives subpoenas and/or requests for information from governmental agencies with respect to our business. We have received a subpoena from the staff of the Securities and Exchange Commission related to the travel expense advancements and reimbursements received by our Former CEO. At this time, the staff's investigation into this matter remains ongoing. The Company is cooperating with the staff but cannot predict with any certainty what the outcome of the foregoing may be.

## **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, 2015.

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

None.

**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**

<b>No.</b>	<b>Description</b>
10.1	Independent Contractor Agreement between the Company and John R. Glass (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on April 22, 2016).
31.1**	Certification of Interim Chief Executive Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).
31.2**	Certification of Interim Chief Financial Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).
32**	Certification of Interim Chief Executive Officer and Interim Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 (Section 906 Certification).
101**	Interactive Data Files.

\*\* 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 9, 2016

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

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