

PROVECTUS BIOPHARMACEUTICALS, INC.

Form 10-Q

November 09, 2016

[Table of Contents](#)

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 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>(I.R.S. Employer</b>
<b>incorporation or organization)</b>	<b>Identification No.)</b>
<b>7327 Oak Ridge Highway, Suite A,</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 \$0.001 per share, as of November 4, 2016 was 243,895,352.

**Table of Contents**

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

<u>Cautionary Note Regarding Forward-Looking Statements</u>	1
<u>Item 1. Financial Statements (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets</u>	2
<u>Condensed Consolidated Statements of Operations</u>	3
<u>Condensed Consolidated Statements of Cash Flow</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	20

**PART II OTHER INFORMATION**

<u>Item 1. Legal Proceedings</u>	22
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	27
<u>Item 3. Defaults Upon Senior Securities</u>	28
<u>Item 4. Mine Safety Disclosures</u>	28
<u>Item 5. Other Information</u>	28
<u>Item 6. Exhibits</u>	29
<b><u>SIGNATURES</u></b>	30

**Table of Contents**

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015 and in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2016), 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;

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; and

our ability to raise capital through our proposed rights offering.

**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

## PROTECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2016 (Unaudited)	December 31, 2015
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 5,178,076	\$ 14,178,902
Short-term receivable - settlement	50,000	500,000
Other current assets	187,222	41,192
<b>Total Current Assets</b>	<b>5,415,298</b>	<b>14,720,094</b>
Equipment and furnishings, less accumulated depreciation of \$460,954 and \$451,028, respectively	75,219	85,145
Patents, net of amortization of \$9,306,197 and \$8,802,857, respectively	2,409,248	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	2,075,509	2,011,735
Other assets	27,000	27,000
<b>Total Assets</b>	<b>\$ 10,685,524</b>	<b>\$ 20,439,812</b>
<b>Liabilities and Stockholders Equity</b>		
<b>Current Liabilities</b>		
Accounts payable trade	\$ 1,486,240	\$ 1,887,171
Accrued consulting expense	192,000	133,282
Accrued settlement expense		1,850,000
Other accrued expenses	355,232	252,418
Warrant liability	3,342,340	
<b>Total Current Liabilities</b>	<b>5,375,812</b>	<b>4,122,871</b>
<b>Commitments and Contingencies Stockholders Equity</b>		
Preferred stock; par value \$0.001 per share; 25,000,000 shares authorized; 240,000 Series B Convertible Preferred shares designated; 18,100 shares and no shares issued and outstanding, respectively	18	
Common stock; par value \$0.001 per share; 400,000,000 authorized; 243,895,352 and 204,979,100 shares issued and outstanding, respectively	243,895	204,979
Additional paid-in capital	205,288,577	196,908,112

Accumulated deficit	(200,222,778)	(180,796,150)
Total Stockholders Equity	5,309,712	16,316,941
Total Liabilities and Stockholders Equity	\$ 10,685,524	\$ 20,439,812

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

## PROVECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	<b>Three Months Ended September 30, 2016</b>	<b>Three Months Ended September 30, 2015</b>	<b>Nine Months Ended September 30, 2016</b>	<b>Nine Months Ended September 30, 2015</b>
Operating expenses				
Research and development	\$ 2,461,407	\$ 2,864,331	\$ 6,874,353	\$ 7,537,440
General and administrative	3,315,555	2,914,375	12,454,661	7,453,401
Total operating loss	(5,776,962)	(5,778,706)	(19,329,014)	(14,990,841)
Investment income	318	1,260	1,985	3,745
Public offering issuance expense (See Note 4)	(436,248)		(436,248)	
Gain (loss) on change in fair value of warrant liability	336,649	(2,607)	336,649	136,987
Net loss	(5,876,243)	(5,780,053)	(19,426,628)	(14,850,109)
Dividend paid in-kind to preferred shareholders	(2,257,432)		(2,257,432)	
Deemed dividend	(726,989)		(726,989)	
Net loss attributable to common shareholders	\$ (8,860,664)	\$ (5,780,053)	\$ (22,411,049)	\$ (14,850,109)
Basic and diluted loss per common share	\$ (0.04)	\$ (0.03)	\$ (0.10)	\$ (0.08)
Weighted average number of common shares outstanding basic and diluted	222,959,570	204,610,080	213,722,977	192,604,128

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

## PROVECTUS BIOPHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW

(Unaudited)

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (19,426,628)	\$ (14,850,109)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	9,926	9,669
Amortization of patents	503,340	503,340
Warrant incentive expense	2,718,407	
Issuance of stock for services	20,163	165,439
Issuance of warrants for services		79,476
Public offering issuance expense (See Note 4)	436,248	
Gain on change in fair value of warrant liability	(336,649)	(136,987)
(Increase) decrease in assets		
Settlement receivable	386,226	653,228
Other current assets	(146,030)	(87,956)
Increase (decrease) in liabilities		
Accounts payable	(400,931)	531,991
Accrued settlement expense	(1,850,000)	
Accrued expenses	161,532	685,354
Net cash used in operating activities	(17,924,396)	(12,446,555)
<b>Cash Flows From Investing Activities</b>		
Capital expenditures		(6,139)
Net cash used in investing activities		(6,139)
<b>Cash Flows From Financing Activities</b>		
Net proceeds from sales of common stock and warrants		13,653,927
Gross proceeds from sales of convertible preferred stock and warrants	6,000,000	
Payment of offering costs in connection with August 2016 financing	(711,470)	
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
Net cash provided by financing activities	8,923,570	13,944,755



Net change in cash and cash equivalents	(9,000,826)	1,492,061
Cash and cash equivalents, at beginning of period	14,178,902	17,391,601
Cash and cash equivalents, at end of period	\$ 5,178,076	\$ 18,883,662
Interest and Taxes:	\$	\$
Supplemental Disclosure of Noncash Investing and Financing Activities:		

	<b>Nine Months Ended September 30, 2016</b>	<b>Nine Months Ended September 30, 2015</b>
Conversion of preferred stock into common stock	\$ 31,066	\$
Contractual dividend on preferred stock	\$ 729,989	\$
Issuance in-kind of preferred stock dividends	\$ 2,257,432	\$

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

PROVECTUS BIOPHARMACEUTICALS, INC.

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 and should be reviewed in conjunction with the Company s audited consolidated financial statements included in Form 10-K for the year ended December 31, 2015 filed with the U.S. Securities and Exchange Commission ( SEC ) on March 30, 2016. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 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 \$5,178,076 at September 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.

On October 13, 2016, the Company received notice from NYSE MKT that NYSE MKT commenced delisting procedures and immediately suspended trading in the Company s common stock and class of warrants that was listed on NYSE MKT. The Company submitted a request for a review of such delisting determination and has until November 11, 2016 to make a written submission to NYSE MKT in connection with this review. The NYSE Regulation staff s delisting action has been stayed pending the outcome of this review.

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 candidates, PV-10 and PH-10, through potential co-development and 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 through the planned Rights Offering (see Footnote 8 to the financial statements, Subsequent Events), it may be forced to implement significant cost cutting measures as early as the first quarter of 2017.

**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.

## Table of Contents

### 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.

### Sequencing Policy

As a result of the issuance of preferred stock and warrants, for which such instruments contained a variable conversion feature with no floor until November 23, 2016, the Company has adopted a sequencing policy in accordance with Accounting Standards Codification ( ASC ) 815-40-35-12 whereby all future instruments may be classified as a derivative liability with the exception of instruments related to share-based compensation issued to employees or directors.

### Fair Value of Financial Instruments

The carrying amounts reported in the condensed consolidated balance sheets for cash and cash equivalents, short-term settlement receivable, other current assets and accounts payable approximate their fair value because of the short-term nature of these items.

The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. Certain derivatives with limited market activity are valued using Level 3 inputs with externally developed models that consider unobservable market parameters. See Note 6.

### Recent Accounting Pronouncements

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.

In September 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which clarifies whether the following items should be categorized as operating, investing or financing in the statement of cash flows: (i) debt prepayments and extinguishment costs, (ii) settlement of zero-coupon debt, (iii) settlement of contingent consideration, (iv) insurance proceeds, (v) settlement of corporate-owned life insurance (COLI) and bank-owned life insurance (BOLI) policies, (vi) distributions from equity method investees, (vii) beneficial interests in securitization transactions, and

## **Table of Contents**

(viii) receipts and payments with aspects of more than one class of cash flows. The new standard takes effect in 2018 for public companies. If an entity elects early adoption, it must adopt all of the amendments 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.

## **Reclassifications**

Certain prior period amounts have been reclassified for comparative purposes to conform to the fiscal 2016 presentation. These reclassifications have no impact on the previously reported net loss.

## **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 September 30, 2016 and 2015, respectively, relate to 101,821,186 and 78,607,893 from warrants, 5,000,000 and 9,545,214 from options and 1,810,000 and 0 from convertible preferred stock.

## **4. Equity Transactions**

### *Common Stock Issued for Services*

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.

During the three months ended September 30, 2015, the Company issued 78,877 shares of common stock to consultants in exchange for services. Consulting costs charged to operations were \$38,439.

### *Warrant Activity*

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.

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.

During the three months ended September 30, 2016, 53,500 warrants were forfeited. During the three months ended September 30, 2015, the Company issued 79,500 fully vested warrants to consultants in exchange for services. Consulting costs charged to operations were \$24,262. During the three months ended September 30, 2015, 1,152,135 warrants were forfeited.

*Warrant Exchange Programs*

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

---

**Table of Contents**

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.

*August 2016 Public Offering*

On August 25, 2016, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock with the Delaware Secretary of State (the Certificate of Designation). The Certificate of Designation provides for the issuance of the Series B Convertible Preferred Stock, par value \$0.001 per share (the Preferred Stock). In the event of the Company's liquidation, dissolution, or winding up, holders of Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to Common Stock immediately prior to such event (without giving effect for such purposes to any beneficial ownership limitation), subject to the preferential rights of holders of any class or series of the Company's capital stock specifically ranking by its terms senior to the Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily. The Preferred Stock has no voting rights.

The holders of Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 8% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Preferred Stock. The dividends become payable, at the Company's option in either cash or in shares of Common Stock, (i) upon any conversion of the Preferred Stock, (ii) on each such other date as the Board may determine, subject to written consent of the holders of Preferred Stock holding a majority of the then issued and outstanding Preferred Stock, (iii) upon the Company's liquidation, dissolution or winding up, and (iv) upon occurrence of a fundamental transaction, which includes any merger or consolidation, sale of all or substantially all of the Company's assets, exchange or conversion of all of the Common Stock by tender offer, exchange offer or reclassification; provided, however, that if Preferred Stock is converted into shares of Common Stock at any time prior to the fifth anniversary of the date of issuance of the Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Preferred Stock before the date of conversion. Make-whole payments are payable at the Company's option in either cash or in shares of Common Stock. With respect to any dividend payments and make-whole payments paid in shares of Common Stock, the number of shares of Common Stock to be issued to a holder of Preferred Stock will be an amount equal to the quotient of (i) the amount of the



dividend payable to such holder divided by (ii) the conversion price then in effect. The dividends related to preferred stock that was not converted during the three months ended September 30, 2016 of \$38,432 represent an in-kind dividend.

On August 30, 2016, the Company closed a public offering of 240,000 shares of its Preferred Stock (which are initially convertible into an aggregate of 24,000,000 shares of the Company's common stock) and warrants initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of \$0.275 per share of common stock (the August 2016 Warrants). The Preferred Stock and August 2016 Warrants were sold together at a price of \$25.00 for a combination of one share of Preferred Stock and 100 August 2016 Warrants to purchase one share of common stock each, resulting in aggregate net proceeds of \$5,288,530 (gross proceeds of \$6,000,000 less issuance costs of \$711,470) to the Company. Maxim Group LLC served as placement agent for the transaction.

The conversion feature embedded within the Preferred Stock is subject to anti-dilution price protection upon the issuance of equity or equity-linked securities within 60 trading days from the date of issuance of the Preferred Stock at an effective common stock purchase price of less than the conversion price of the Preferred Stock then in effect, subject to certain exceptions as provided in the Certificate of Designation. In addition, if the conversion price in effect on the 60th trading day following the date of issuance of the Preferred Stock exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period

---

**Table of Contents**

commencing on the date of issuance of the Preferred Stock and ending on the 60th trading day following the date of issuance of the Preferred Stock (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period) (the Adjusted Conversion Price ), then the conversion price shall be reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the Certificate of Designation. In either case, if a holder of Preferred Stock converts its shares of Preferred Stock prior to any such price reset event, then such holder will receive additional shares of common stock equal to the number of shares of common stock that would have been issued assuming for such purposes the Adjusted Conversion Price were in effect at such time less the shares issued at the then Conversion Price (subject to being held in abeyance based on beneficial ownership limitations); provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the Offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event. During the three months ended September 30, 2016, investors converted 221,900 shares of Preferred Stock and Preferred Stock dividends (including make-whole payments) into 31,066,000 shares of Common Stock.

The August 2016 Warrants expire on August 30, 2021. The exercise price of the August 2016 Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, if the exercise price in effect on the 60th trading day following the date of issuance of the August 2016 Warrants exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on the date of issuance of the August 2016 Warrants and ending on the 60th trading day following the date of issuance of the August 2016 Warrants (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period) (the Adjusted Exercise Price ), then (i) the exercise price shall be reset to the Adjusted Exercise Price (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the August 2016 Warrants, and (ii) the number of shares of common stock issuable upon exercise of the August 2016 Warrants will be reset to equal the number of shares of common stock issuable upon conversion of Preferred Stock after giving effect to the adjusted conversion price or adjusted exercise price, as applicable. If a holder of August 2016 Warrants exercises its August 2016 Warrants prior to such repricing, then such holder will receive shares of common stock equal to the difference between the exercise price and the Adjusted Exercise Price; provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the Offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

The Series B Preferred Stock does not contain a redemption provision and an overall analysis of its features performed by the Company determined that it is more akin to equity and therefore, has been classified within stockholders' equity on the condensed consolidated balance sheet. While the embedded conversion option ( ECO ) is subject to an anti-dilution price adjustment, since the ECO is clearly and closely related to the equity host, it is not required to be bifurcated and accounted for as a derivative liability under ASC 815. To analyze whether the Preferred Stock included a beneficial conversion feature ( BCF ), the Company allocated the \$6,000,000 of the gross proceeds between the August 2016 Warrants and the Preferred Stock. The Company allocated the commitment date fair value of \$3,678,989 to the August 2016 Warrants (which is allocated at fair value because the August 2016 Warrants were determined to be derivative liabilities as discussed in Note 6) resulting in an amount allocated to the Preferred Stock of \$2,321,011. Next, the Company computed the number of shares of Common Stock issuable at the commitment date to be 24,000,000 in order to arrive at an effective conversion price of \$0.097 per share. When compared to the market price of the Company's Common Stock of \$0.127 per share as of the commitment date, it was determined that a BCF did exist and, as a result, the Company recorded a contractual dividend in net loss available to common stockholders of \$726,989.

During the three months ended September 30, 2016, a number of investors converted their Preferred Stock such that they were entitled to dividends, including a make-whole payment, that the Company elected to pay in shares of Common Stock. As a result, the Company issued 8,876,000 shares of Common Stock related to the Preferred Stock dividends during the three months ended September 30, 2016. Since the investors did not pay any additional consideration for such shares (and the impact of the time-based dividend was immaterial due to the majority of conversions occurring on the date of issuance), the Company recognized dividend paid in kind to preferred shareholders of \$2,219,000 associated with the make-whole payment which was equal to the number of shares multiplied by the market price of the Company's Common Stock of \$0.127 per share as of the commitment date. The net carrying value of the Preferred Stock is \$2,045,789 (gross proceeds of \$6,000,000 less preferred stock discount associated with August 2016 Warrants of \$3,678,989 less issuance costs allocated to Preferred Stock of \$275,222). Since the Preferred Stock doesn't contain a redemption provision, it is not probable that the Preferred Stock will become redeemable, therefore the preferred stock discount is not amortized.

On November 23, 2016, when the Preferred Stock conversion price becomes fixed and, as a result, the contingency is resolved, the Company will analyze for a BCF, however, the maximum cumulative BCF that can be recognized is equal to the carrying value of the Preferred Stock. As of September 30, 2016, the Company had recorded BCFs of \$726,989.

---

**Table of Contents**

The August 2016 Warrants were determined to be derivative liabilities due to the presence of an anti-dilution feature whereby the Company may not have a sufficient number of authorized and unissued shares, which results in the assumption of a cash settlement of the warrant.

Utilizing a Monte Carlo valuation method, a valuation expert determined that the August 2016 Warrants had an issuance date value of \$3,678,989 and a value on September 30, 2016 of \$3,342,340, a decrease of \$336,649, which will be recognized as a gain on the change in fair value of derivative liabilities. At issuance, the fair value was recognized as a liability (with a corresponding debit to additional paid-in capital for the preferred stock discount) and that liability will be marked-to-the-market on November 23, 2016, when the exercise price becomes fixed, and that amount will be reclassified to equity because the August 2016 Warrants will no longer be subject to the anti-dilution adjustment.

In connection with the closing of the Offering, the Company incurred \$711,470 of cash issuance costs. \$436,248 of the issuance costs were allocated to the August 2016 Warrants (the August 2016 Warrants comprised \$3,678,989, or 61%, of the aggregate gross proceeds of \$6,000,000; 61% of the aggregate issuance costs of \$711,470 is \$436,248), which are classified as a derivative liability and, as a result, were expensed immediately (and included within other expense (non-operating) on the condensed consolidated statement of operations) and \$275,222 of the issuance costs were allocated to the Preferred Stock, which is classified as equity and, as a result, were charged against additional paid-in capital.

**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. Fair Value of Financial Instruments**

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

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

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

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

In determining the appropriate levels, the Company performs a detailed analysis of the assets and liabilities that are measured and reported on a fair value basis. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs are classified as Level 3. The fair value of certain of the Company's financial instruments, including Cash and cash equivalents and Accounts payable, approximates the carrying value due to the relatively short maturity of such instruments. The fair value of derivative instruments is determined by management with the assistance of an independent third party valuation specialist. The warrant liability is a derivative instrument and is classified as Level 3. The Company used the Monte-Carlo Simulation model to estimate the fair value of the warrants using the following assumptions: expected volatility of 107.8%-108.6%, risk-free rate of 0.88%-0.92%, expected term of 4.91-5.00 years, and expected dividends of 0.00%.

**Table of Contents**

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

	Total	Level 1	Level 2	Level 3
<b>Derivative instruments:</b>				
Warrant liability at September 30, 2016	\$ 3,342,340	\$	\$	\$ 3,342,340
Warrant liability at December 31, 2015	\$	\$	\$	\$

A reconciliation of the warranty liability measured at fair value on a recurring basis with the use of significant unobservable inputs (Level 3) from December 31, 2015 to September 30, 2016 follows:

Balance at December 31, 2015	\$
Issuance of warrants	3,678,989
Gain on change in fair value of warrant liability	(336,649)
Exercise of warrants	
Balance at September 30, 2016	\$ 3,342,340

**7. Litigation***Kleba Shareholder Derivative Lawsuit*

On January 2, 2013, Glenn Kleba, derivatively on behalf of the Company, filed a shareholder derivative complaint in the Circuit Court for the State of Tennessee, Knox County (the Court), against the Former CEO, 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 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

**Table of Contents**

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 plaintiffs' 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 September 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 September 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 September 30, 2016, and a total of \$450,000 was repaid for the nine months ended September 30, 2016. An additional \$19,962 of the settlement discount was amortized as of September 30, 2016, and a total of \$63,774 was amortized for the nine months ended September 30, 2016. \$167,743 of the settlement discount was amortized as of September 30, 2016. The remaining balance due the Company as of September 30, 2016 is \$2,125,509, including a reserve for uncollectibility of \$870,578 in connection with the resignation of the Former CEO, with a present value discount remaining of \$133,912. 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 BTM, 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.

---

**Table of Contents**

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. On September 16, 2016, the Lead Plaintiff notified the court that approximately 6,300 stockholders did not receive notification of the proposed settlement until late August 2016 because of the delayed receipt of potential Settlement Class Member information from a number of brokers. As a result, on September 22, 2016, the parties filed a joint motion requesting that the court extend the deadlines to file a Proof of Claim, request exclusion from the settlement, or file an objection to the settlement, and that the court schedule a continued settlement hearing. The court granted the motion, cancelling the settlement hearing that had been set for September 26 and re-setting the hearing to take place on December 12, 2016. The court set a new deadline of November 10, 2016 for objections and requests for exclusion, and November 25, 2016 for submitting proofs of claim. 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

## **Table of Contents**

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. On August 26, 2016, the court held a final hearing on the fairness of the settlement and entered an order approving the settlement and dismissing the action with prejudice.

### *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 alleges 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, the Company is seeking for the damages to be joint and several as to the Defendants and that punitive damages be awarded against the Former CEO in the Company's favor. The Company is also seeking foreclosure of the Company's first-priority security interest in the 1,000,000 shares of common stock granted by Dr. Dees to the Company as collateral pursuant to that certain Stock Pledge Agreement dated October 3, 2014, between Dr. Dees and the Company in order to secure Dr. Dees' obligations under the Kleba Settlement Agreement. The United States District Court for the Eastern District of Tennessee at Knoxville entered a default judgment against Dr. Dees on July 20, 2016; however, the Company cannot predict when these shares will be recovered by the Company. The Court recently issued a Temporary Restraining Order upon the Company's application for same upon notice that Dr. Dees was attempting to sell his shares of the Company's common stock. The Temporary Restraining Order was converted to a Preliminary Injunction on September 16, 2016, which order will remain in place until the trial of the underlying lawsuit absent further court order or agreement of the parties, and the Company is presently engaged in discovery regarding damages.

---

**Table of Contents***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.

**8. Subsequent Events**

The Company has evaluated subsequent events through the date of the filing of these financial statements.

*Rights Offering*

On October 5, 2016, the Company filed a registration statement on Form S-1 with the Securities and Exchange Commission, as amended on November 1, 2016, to issue subscription rights ( Rights ) to the Company's existing common stockholders to purchase units ( Units ) consisting of shares of common stock and warrants to purchase shares of common stock (the Rights Offering ). Each whole warrant will be exercisable for one share of common stock. Each Right will entitle holders of the Company's common stock to purchase one Unit. The Rights Offering also contains an over-subscription privilege allowing stockholders who exercise their subscription rights in full to purchase other stockholders' unsubscribed Units under certain circumstances. The Company is seeking to raise \$17,500,000 in gross proceeds from the Rights Offering. The Company has the ability to elect to increase the size of the Rights Offering by up to 20%, which, if so increased, would result in gross proceeds of \$21,000,000 from the Rights Offering. The Company intends to use approximately \$15 million of the net proceeds from the Rights Offering for clinical development, including approximately \$5 million to complete its ongoing phase 3 clinical trial of PV-10 to treat locally advanced cutaneous melanoma, approximately \$5 million to complete its phase 1b/2 combination study of PV-10 and Merck's KEYTRUDA in late stage melanoma and approximately \$5 million to complete its phase 1b/2 study of PV-10 in liver cancer, and the Company intends to use the remaining net proceeds for working capital and general corporate purposes. If the Company sells all of the Units subject to the Rights Offering, the Company will have sufficient cash on hand to fund all of its research and development and other capital needs through 2017.

On November 2, the Company filed a definitive proxy statement on Schedule 14A with the Securities and Exchange Commission, pursuant to which the Company is soliciting stockholders to (i) approve a proposed amendment to the Company's Certificate of Incorporation to authorize an increase in the number of authorized shares of common stock to an amount that will be sufficient to, in part, allow the Company to issue the shares of common stock that will be contained in the Units (if the maximum amount of Units is sold in the Rights Offering) and the shares of common stock that will be issuable upon exercise of the warrants (if the maximum amount of Units is sold in the Rights Offering) and (ii) authorize the Company's board of directors to amend the Company's certificate of incorporation, as amended, to effect a reverse stock split of the Company's common stock at a ratio of between 1-for-10 and 1-for-50, such ratio to be determined by the board of directors in its sole discretion (the Reverse Stock Split ) at a special meeting of stockholders scheduled to be held on November 28, 2016 (the Special Meeting ). There is no assurance, however, that either or both proposals will be approved by the Company's stockholders, that the registration statement with respect to the Rights Offering will be declared effective, that the Rights Offering will be successful or that the Company will issue any Rights, Units, common stock or warrants pursuant to the Rights Offering.

*Series B Convertible Preferred Stock Conversions*

On November 3, 2016, a holder of Preferred Stock converted 8,000 shares of Preferred Stock and Preferred Stock dividends (including make-whole payments) into 1,120,000 shares of common stock pursuant to the terms of the Certificate of Designation for the Preferred Stock.

## **Table of Contents**

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

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the accompanying unaudited financial statements, our Annual Report on Form 10-K for the year ended December 31, 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 Nine Months Ended September 30, 2016 and September 30, 2015**

###### *Revenues*

We had no revenue during the three and nine months ended September 30, 2016 and 2015.

###### *Research and Development*

Research and development costs of \$2,461,407 for the three months ended September 30, 2016 included amortization of patents of \$167,780, payroll of \$206,563, consulting and contract labor of \$1,866,360, legal of \$109,828, insurance of \$65,772, lab supplies and pharmaceutical preparations of \$23,975, rent and utilities of \$18,195, and depreciation expense of \$2,934. Research and development costs of \$2,864,331 for the three months ended September 30, 2015



included amortization of patents of \$167,780, payroll of \$542,851, consulting and contract labor of \$1,538,362, legal of \$11,664, insurance of \$60,598, lab supplies and pharmaceutical preparations of \$517,529, rent and utilities of \$22,256, and depreciation expense of \$3,291. The overall decrease in research and development costs is due primarily to a decrease of approximately \$500,000 in lab supplies and pharmaceutical preparations due to lower investigational drug costs for the phase 3 study of PV-10 in locally advanced cutaneous melanoma and the phase 2 study of PH-10 mechanism of action, both of which commenced in the quarter ended March 31, 2015, as well as the phase 1b/2 study of PV-10 in combination with pembrolizumab which commenced in the quarter ended September 30, 2015, and is also due to approximately \$300,000 in decreased payroll expense due to the departure of the Former CEO. This decrease is offset partially by approximately \$300,000 in increased consulting and contract labor due to the ongoing PV-10 related clinical studies.

Research and development costs of \$6,874,353 for the nine months ended September 30, 2016 included amortization of patents of \$503,340, payroll of \$737,704, consulting and contract labor of \$5,054,234, legal of \$256,238, insurance of \$177,567, lab supplies and pharmaceutical preparations of \$63,718, rent and utilities of \$71,626, and depreciation expense of \$9,926. Research and development costs of \$7,537,440 for the nine months ended September 30, 2015 included amortization of patents of \$503,340, payroll of \$1,372,200, consulting and contract labor of \$4,142,207, legal of \$222,623, insurance of \$127,432, lab supplies and pharmaceutical preparations of \$1,096,333, rent and utilities of \$63,636, and depreciation expense of \$9,669. The overall decrease in research and development costs is due primarily to a decrease of approximately \$1,000,000 in lab supplies and pharmaceutical preparations due to lower investigational drug costs for the phase 3 study of PV-10 in locally advanced cutaneous melanoma and the phase 2 study of PH-

## **Table of Contents**

10 mechanism of action, both of which commenced in the quarter ended March 31, 2015, as well as the phase 1b/2 study of PV-10 in combination with pembrolizumab which commenced in the quarter ended September 30, 2015, and is also due to approximately \$600,000 in decreased payroll expense due to the departure of the Former CEO. This decrease is offset partially by approximately \$900,000 in increased consulting and contract labor due to the ongoing PV-10 related clinical studies.

### *General and Administrative*

General and administrative expenses increased by \$401,180 in the three months ended September 30, 2016 to \$3,315,555 from \$2,914,375 for the three months ended September 30, 2015. General and administrative expenses were very similar for both periods except for two primary accounts. Approximately \$100,000 in increased expense is due to higher total of investor and public relations expense during the three months ended September 30, 2016 versus the three months ended September 30, 2015 due primarily to efforts to maximize the visibility and awareness of the Company in the marketplace. Approximately \$300,000 in increased expense is due to legal compliance during the three months ended September 30, 2016 versus the three months ended September 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 \$5,001,260 in the nine months ended September 30, 2016 to \$12,454,661 from \$7,453,401 for the nine months ended September 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 nine months ended September 30, 2016 versus the nine months ended September 30, 2015, as described in Note 4(c) to the accompanying financial statements. Approximately \$1.3 million in increased expense is due to higher total of investor and public relations expense during the nine months ended September 30, 2016 versus the nine months ended September 30, 2015 due primarily to efforts to maximize the warrant exchange transaction described in Note 4(c) to the accompanying financial statements. Approximately \$900,000 in increased expense is due to legal compliance during the nine months ended September 30, 2016 versus the nine months ended September 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.

### *Investment Income*

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

### *Public offering issuance expense*

The change in public offering expense increased by \$436,248 in the three months ended September 30, 2016 to a loss of \$436,248. There is no expense in 2015 since the financing that results in this public offering issuance expense was only incurred in the three months ended September 30, 2016.

The change in public offering expense increased by \$436,248 in the nine months ended September 30, 2016 to a loss of \$436,248. There is no expense in 2015 since the financing that results in this public offering issuance expense was only incurred in the three months ended September 30, 2016.

### *Gain/Loss on change in fair value of warrant liability*

The change in fair value of warrant liability increased by \$339,256 in the three months ended September 30, 2016 to a gain of \$336,649 from a loss of \$2,607 for the three months ended September 30, 2015. See Note 4, *August 2016 Public Offering*.

The change in fair value of warrant liability increased by \$199,662 in the nine months ended September 30, 2016 to a gain of \$336,649 from a gain of \$136,987 for the nine months ended September 30, 2015. See Note 4, *August 2016 Public Offering*.

### **Liquidity and Capital Resources**

The Company's cash and cash equivalents were \$5,178,076 at September 30, 2016, compared with \$14,178,902 at December 31, 2015. The accompanying condensed consolidated financial statements for the nine months ended September 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 \$201 million as of September 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

## Table of Contents

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.

On August 30, 2016, we closed a public offering of 240,000 shares of our Series B Convertible Preferred Stock, par value \$0.001 per share (the Preferred Stock ) (which shares are initially convertible into an aggregate of 24,000,000 shares of our common stock), and warrants (the August 2016 Warrants ) initially exercisable to purchase an aggregate of 24,000,000 shares of common stock at an exercise price of \$0.275 per share of common stock. The Preferred Stock and August 2016 Warrants were sold together at a price of \$25.00 for a combination of one share of Preferred Stock and 100 August 2016 Warrants to purchase one share of common stock each, resulting in gross offering proceeds of \$6,000,000 to us before the payment of placement agent fees and expenses related to the offering.

In November or December 2016, we intend to distribute to holders of our common stock, par value \$0.001 per share, at no charge, non-transferable subscription rights to purchase Units. Each Unit consists of a to be determined number of shares of common stock and a to be determined number of warrants representing the right to purchase one share of our common stock, which we refer to as the Warrants. Each whole Warrant will be exercisable for one share of our common stock. We refer to this offering as the Rights Offering. In the proposed Rights Offering, each stockholder will receive one subscription right for each share of common stock owned at 5:00 p.m., Eastern Time, on the to be determined record date of the Rights Offering, or the Record Date. The common stock and the Warrants comprising the Units will separate upon the closing of the Rights Offering and will be issued separately but may only be purchased as a Unit, and the Units will not trade as a separate security. The subscription rights will not be tradable. There can be no assurance, however, that the registration statement with respect to the Rights Offering will be declared effective, that the Rights Offering will be successful or that the Company will issue any Units, common stock or Warrants pursuant to the Rights Offering

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 candidates, PV-10 and PH-10, through potential co-development and 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 through the planned Rights Offering (see Footnote 8 to the financial statements, Subsequent Events), it may be forced to implement significant cost cutting measures as early as the first quarter of 2017.

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, MENAT, Brazil, Israel 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.

## **Table of Contents**

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 Securities and Exchange Commission to notify the market. Furthermore, the strategy of the Company for the benefit of stockholders is a series of partnerships followed by an acquisition of the Company along the lines of Celgene-Abraxis, although there can be no assurance that such partnerships or acquisition will occur. An interim transaction could be a co-development deal like Roche-NewLink, Bristol-Celldex or AstraZeneca-Incyte. The Company is not in discussions regarding the sale of its business, and there can be no assurance that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

We have signed multiple advisory agreements with accomplished individuals and organizations to help identify partners, including collaborators, distribution and joint venture partners, and licensees for PV-10 in China, Brazil and Latin America in general, India and the Indian Subcontinent, MENAT, Russia, European Union ( EU ), Israel, 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, Israel, 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 that the Company will be able to monetize PV-10 or PH-10 in the manner described herein.

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. 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.

**Table of Contents**

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

We had no holdings of financial or commodity instruments as of September 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 August 2016 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 \$3,342,340 as of September 30, 2016.

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 developments 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 September 30, 2016, the end of the fiscal quarter covered by this Quarterly Report on Form 10-Q. Based on that evaluation and as discussed below, 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. Our remediation plan is still in process and as such, these material weaknesses continued to exist at September 30, 2016.

***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.

## **Table of Contents**

As such, 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

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.

---

**Table of Contents**

**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS.**

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

*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 September 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 September 30, 2016, and a total of \$450,000 was repaid for the nine months ended September 30, 2016.

---

**Table of Contents**

An additional \$19,962 of the settlement discount was amortized as of September 30, 2016, and a total of \$63,774 was amortized for the nine months ended September 30, 2016. \$167,743 of the settlement discount was amortized as of September 30, 2016. The remaining balance due the Company as of September 30, 2016 is \$2,125,509, including a reserve for uncollectibility of \$870,578 in connection with the resignation of the Former CEO, with a present value discount remaining of \$133,912. 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 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.

---

**Table of Contents**

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. On September 16, 2016, the Lead Plaintiff notified the court that approximately 6,300 stockholders did not receive notification of the proposed settlement until late August 2016 because of the delayed receipt of potential Settlement Class Member information from a number of brokers. As a result, on September 22, 2016, the parties filed a joint motion requesting that the court extend the deadlines to file a Proof of Claim, request exclusion from the settlement, or file an objection to the settlement, and that the court schedule a continued settlement hearing. The court granted the motion, cancelling the settlement hearing that had been set for September 26 and re-setting the hearing to take place on December 12, 2016. The court set a new deadline of November 10, 2016 for objections and requests for exclusion, and November 25, 2016 for submitting proofs of claim. 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.

## **Table of Contents**

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. On August 26, 2016, the court held a final hearing on the fairness of the settlement and entered an order approving the settlement and dismissing the action with prejudice.

### *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 alleges 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. We are also seeking foreclosure of our first-priority security interest in the 1,000,000 shares of common stock granted by Dr. Dees to the Company as collateral pursuant to that certain Stock Pledge Agreement dated October 3, 2014, between Dr. Dees and the Company in order to secure Dr. Dees' obligations under the Kleba Settlement Agreement. The United States District Court for the Eastern District of Tennessee at Knoxville entered a default judgment against Dr. Dees on July 20, 2016; however, the Company cannot predict when these shares will be recovered by the Company. The Court recently issued a Temporary Restraining Order upon the Company's application

for same upon notice that Dr. Dees was attempting to sell his shares of the Company's common stock. The Temporary Restraining Order was converted to a Preliminary Injunction on September 16, 2016, which order will remain in place until the trial of the underlying lawsuit absent further court order or agreement of the parties, and the Company is presently engaged in discovery regarding damages.

*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 other than as set forth below.

**Table of Contents**

***There is substantial doubt as to our ability to continue as a going concern.***

Our cash and cash equivalents were \$5,178,076 at September 30, 2016, compared with \$14,178,902 at December 31, 2015. We continue to incur significant operating losses, and management expects that significant on-going operating expenditures will be necessary to successfully implement our business plan and develop and market our products. These circumstances raise substantial doubt about our ability to continue as a going concern. Implementation of our plans and our ability to continue as a going concern will depend upon our ability to develop PV-10 and raise additional capital.

Management believes that we have access to capital resources through possible public or private equity offerings (including the planned Rights Offering), exchange offers, debt financings, corporate collaborations or other means. In addition, we continue to explore opportunities to strategically monetize our lead drug candidates, PV-10 and PH-10, through potential co-development and licensing transactions, although there can be no assurance that we will be successful with such plans. We have historically been able to raise capital through equity offerings, although no assurance can be provided that we will continue to be successful in the future. If we are unable to raise sufficient capital through the Rights Offering or otherwise, we may be forced to implement significant cost cutting measures as early as the first quarter of 2017.

***Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.***

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Among other things, these provisions will:

permit our board of directors to issue up to 25,000,000 shares of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of the common stock;

provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by our then-current Board of Directors, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline.

***NYSE MKT has taken actions toward delisting our common stock, including suspending trading in our common stock.***

Pursuant to Section 1003(f)(v) of the NYSE MKT Company Guide, on October 13, 2016, the NYSE MKT immediately suspended trading in shares of our common stock and class of warrants listed on the NYSE MKT and commenced delisting procedures as a result of the abnormally low trading price of our common stock. On October 20, 2016, we submitted a request for a review of such delisting determination and have until November 11, 2016 to make a written submission to NYSE MKT in connection with this review. The NYSE Regulation staff's delisting action has been stayed pending the outcome of this review. In the event our appeal is unsuccessful and our common stock is delisted from the NYSE MKT, we may need to make filings and obtain approval from certain state regulators for the issuance of the securities being offered pursuant to the Rights Offering, which could delay and increase the costs of the Rights Offering, and possibly make the Rights Offering unavailable in certain states.

**Table of Contents**

***Price protection provisions attached to the Preferred Stock and August 2016 Warrants may reduce the amount of capital we may receive upon conversion of such Preferred Stock and exercise of such August 2016 Warrants and may also result in dilution to our stockholders.***

The conversion price of the Preferred Stock is subject to anti-dilution price protection upon the issuance of equity or equity-linked securities between August 30, 2016, the date of issuance of the Preferred Stock and August 2016 Warrants, and November 23, 2016, which we refer to as the Price Reset Date, at an effective common stock purchase price of less than the conversion price then in effect, subject to certain exceptions as provided in the Certificate of Designation. In addition, if the conversion price in effect on the Price Reset Date exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on August 30, 2016 and ending on the Price Reset Date (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Conversion Price, then the conversion price shall be reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the Certificate of Designation. In either case, if a holder of Preferred Stock converts its shares of Preferred Stock prior to any such price reset event, then such holder will receive additional shares of common stock equal to the number of shares of common stock that would have been issued assuming for such purposes the Adjusted Conversion Price were in effect at such time less the shares issued at the then Conversion Price (subject to being held in abeyance based on beneficial ownership limitations); provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

The exercise price of the August 2016 Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. In addition, if the exercise price in effect on the Price Reset Date exceeds 85% of the average of the 45 lowest volume weighted average trading prices of the common stock during the period commencing on August 30, 2016 and ending on the Price Reset Date (as adjusted for stock splits, stock dividends, recapitalizations, reorganizations, reclassification, combinations, reverse stock splits or other similar events during such period), which we refer to as the Adjusted Exercise Price, then (i) the exercise price shall be reset to the Adjusted Exercise Price (and without giving effect to any prior conversions) and shall be further subject to adjustment as provided in the August 2016 Warrants, and (ii) the number of shares of common stock issuable upon exercise of the August 2016 Warrants will be reset to equal the number of shares of common stock issuable upon conversion of Preferred Stock after giving effect to the Adjusted Conversion Price or Adjusted Exercise Price, as applicable. If a holder of August 2016 Warrants exercises its August 2016 Warrants prior to such repricing, then such holder will receive shares of common stock equal to the difference between the exercise price and the Adjusted Exercise Price; provided, however, that only the initial purchaser of Preferred Stock and August 2016 Warrants in the offering will receive the benefit of such price protection and such issuance of shares of common stock upon a price reset event.

Because these price protection provisions may have the effect of lowering the price at which shares of our common stock are issued upon conversion of the Preferred Stock and exercise of the August 2016 Warrants, if such August 2016 Warrants are exercised for cash, we will receive reduced proceeds. Any such reduction in proceeds may have an adverse effect on our future working capital requirements. In addition, if the price protection provisions are triggered on the Price Reset Date, our stockholders could experience dilution as a result of the additional shares of common stock that the Company will need to issue to holders of Preferred Stock who converted their shares of Preferred Stock prior to the Price Reset Date and holders of August 2016 Warrants who exercised their Warrants prior to the Price Reset Date.

***We may be subject to liquidated damages if we do not have a sufficient number of shares of common stock authorized for issuance to satisfy our obligation to issue additional shares of common stock pursuant to the price***

*protection provisions attached to the Preferred Stock and August 2016 Warrants.*

If we do not receive stockholder approval for the amendment to our certificate of incorporation to increase the number of shares of our common stock that we are authorized to issue or for the Reverse Stock Split at the Special Meeting, we will not have a sufficient number of authorized shares of common stock to meet our obligation to issue additional shares of common stock to satisfy the price protection provisions of the Preferred Stock and August 2016 Warrants. If we fail to meet our obligation to issue additional shares of common stock to satisfy the price protection provisions of the Preferred Stock and August 2016 Warrants, or fail to issue shares of common stock upon conversion of the Preferred Stock or the exercise of the August 2016 Warrants in accordance with the Certificate of Designation or the terms of the August 2016 Warrants, as applicable, we may be subject to liquidated damages, among other remedies under the Certificate of Designation and the terms of the August 2016 Warrants, as applicable. Accordingly, we will be required to continue to seek stockholder approval of an increase in the number of shares of common stock we are authorized to issue and/or the Reverse Stock Split to meet such obligation.

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

None.

**Table of Contents**

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

None.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

None.



**Table of Contents**

**ITEM 6. EXHIBITS**

**Exhibit**

<b>No.</b>	<b>Description</b>
3.1	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's current report on Form 8-K filed on August 25, 2016).
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed on August 25, 2016).
10.1	Form of Securities Purchase Agreement between Provectus Biopharmaceuticals, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on August 25, 2016) (exhibits and schedules have been omitted, and the Company agrees to furnish supplementally to the Commission a copy of any omitted exhibits and schedules upon request).
10.2	Warrant Agency Agreement, dated August 30, 2016, by and between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on August 30, 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.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PROVECTUS BIOPHARMACEUTICALS, INC.

November 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)

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

<b>No.</b>	<b>Description</b>
3.1	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's current report on Form 8-K filed on August 25, 2016).
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed on August 25, 2016).
10.1	Form of Securities Purchase Agreement between Provectus Biopharmaceuticals, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on August 25, 2016) (exhibits and schedules have been omitted, and the Company agrees to furnish supplementally to the Commission a copy of any omitted exhibits and schedules upon request).
10.2	Warrant Agency Agreement, dated August 30, 2016, by and between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on August 30, 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.