

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark one)

Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 30, 2017

Or

Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number 001-36351

**PLx Pharma Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

State or other jurisdiction of  
incorporation or organization

**8285 El Rio Street, Ste. 130  
Houston, Texas**

(Address of principal executive offices)

**46-4995704**

(I.R.S. Employer  
Identification No.)

**77054**

(Zip Code)

Registrant's telephone number, including area code **(713) 842-1249**

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 9, 2017, there were 8,688,393 shares of common stock, \$0.001 par value, issued and outstanding.

# PLx Pharma Inc.

## Table of Contents

	Page
<b>PART I - FINANCIAL INFORMATION</b>	<b>3</b>
Item 1. Unaudited Consolidated Financial Statements	3
Unaudited Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016	3
Unaudited Consolidated Statements of Operations for the three and six months ended June 30, 2017 and 2016	4
Unaudited Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the six months ended June 30, 2017	5
Unaudited Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016	6
Notes to Unaudited Consolidated Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3. Quantitative and Qualitative Disclosures about Market Risk	26
Item 4. Controls and Procedures	26
<b>PART II - OTHER INFORMATION</b>	<b>27</b>
Item 1. Legal Proceedings	27
Item 1A. Risk Factors	27
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	44
Item 3. Defaults Upon Senior Securities	44
Item 4. Mine Safety Disclosure	44
Item 5. Other Information	45
Item 6. Exhibits	45
Signatures	46
Certificates	

## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In this quarterly report, we refer to PLx Pharma Inc., together with its subsidiaries, as the “Company,” “we,” “our” or “us.” All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect” or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II Item 1A “Risk Factors.” In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to bring Aspertec 81 mg and 325 mg to market-readiness;
- our ability to maintain regulatory approval of Aspertec 325 mg or obtain and maintain regulatory approval of Aspertec 81 mg and any future product candidates;
- the benefits of the use of Aspertec;
- the projected dollar amounts of future sales of established and novel gastrointestinal (“GI”)—safer technologies for non-steroidal anti-inflammatory drugs (“NSAIDs”) and other analgesics;
- our ability to successfully commercialize our Aspertec products, or any future product candidates;
- the rate and degree of market acceptance of our Aspertec products or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to scale up manufacturing of our Aspertec products to commercial scale;
- our ability to successfully build a specialty sales force and commercial infrastructure or collaborate with a firm that has these capabilities;
- our ability to compete with companies currently producing GI-safer technologies for NSAIDs and other analgesics;
- our reliance on third parties to conduct our clinical studies;
- our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us;
- our reliance on our collaboration partners’ performance over which we do not have control;
- our ability to retain and recruit key personnel, including development of a sales and marketing function;
- our ability to obtain and maintain intellectual property protection for our Aspertec products or any future product candidates;
- the actual receipt and timing of any milestone payments or royalties from our collaborators;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”);

- our ability to identify, develop, acquire and in-license new products and product candidates;
- our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this quarterly report speaks only as of the date on which it is made. We disclaim any duty to update any of these forward looking statements after the date of this quarterly report to confirm these statements to actual results or revised expectations.

Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this quarterly report speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

#### **NOTE REGARDING TRADEMARKS**

We own various U.S. federal trademark registrations and applications and unregistered trademarks and service marks, including:

- Aspertec™; and
- PLxGuard™.

Solely for convenience, the trademarks and trade names in this quarterly report are sometimes referred to without the ™ symbol, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

**PART I. FINANCIAL INFORMATION**  
**ITEM 1. UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**

**PLx Pharma Inc.**

**UNAUDITED CONSOLIDATED BALANCE SHEETS**

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 25,079,590	\$ 59,335
Accounts receivable, net	381,028	5,077
Inventory, net	394,740	116,726
Contract manufacturing deposit	657,400	-
Prepaid expenses	359,293	4,652
Security deposit	4,064	4,064
<b>TOTAL CURRENT ASSETS</b>	<u>26,876,115</u>	<u>189,854</u>
<b>NON-CURRENT ASSETS</b>		
Property and equipment, net	513,986	426,634
Security deposit - noncurrent	56,630	-
Intangible assets, net	2,300,000	-
Goodwill	2,061,022	-
<b>TOTAL ASSETS</b>	<u>\$ 31,807,753</u>	<u>\$ 616,488</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 476,039	\$ 862,995
Accrued severance	2,284,000	-
Accrued interest	-	64,781
Accrued interest - related parties	-	30,344
Convertible notes payable	-	1,297,700
Convertible notes payable - related parties	-	480,000
<b>TOTAL CURRENT LIABILITIES</b>	<u>2,760,039</u>	<u>2,735,820</u>
<b>NON-CURRENT LIABILITIES</b>		
Deferred revenue	200,000	200,000
Warrant liability	14,130,126	-
<b>TOTAL LIABILITIES</b>	<u>17,090,165</u>	<u>2,935,820</u>
<b>Commitments and contingencies (Note 7)</b>		
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Preferred stock; \$0.001 par value; 10,000,000 shares authorized; none issued and outstanding	-	-
Common stock; \$0.001 par value; 100,000,000 shares authorized; 8,686,010 and 4,383,433 shares issued and outstanding, respectively	8,686	4,383
Additional paid-in capital	70,357,493	49,661,802
Accumulated deficit	(55,648,591)	(51,985,517)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>14,717,588</u>	<u>(2,319,332)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>\$ 31,807,753</u>	<u>\$ 616,488</u>

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>REVENUES:</b>				
Federal grant	\$ 375,951	\$ -	\$ 375,951	\$ -
License revenue	-	20,000	-	20,000
<b>TOTAL REVENUES</b>	<b>375,951</b>	<b>20,000</b>	<b>375,951</b>	<b>20,000</b>
<b>OPERATING EXPENSES:</b>				
Research and development	626,296	13,081	754,635	53,041
General and administrative	4,024,658	1,450,747	5,241,729	2,302,316
<b>TOTAL OPERATING EXPENSES</b>	<b>4,650,954</b>	<b>1,463,828</b>	<b>5,996,364</b>	<b>2,355,357</b>
<b>OPERATING LOSS</b>	<b>(4,275,003)</b>	<b>(1,443,828)</b>	<b>(5,620,413)</b>	<b>(2,335,357)</b>
<b>OTHER INCOME (EXPENSE)</b>				
Interest income	14,482	309	14,482	378
Interest expense	(642,006)	(24,608)	(723,563)	(34,041)
Change in fair value of warrant liability	1,746,420	-	1,746,420	-
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>1,118,896</b>	<b>(24,299)</b>	<b>1,037,339</b>	<b>(33,663)</b>
<b>LOSS BEFORE INCOME TAX BENEFIT</b>	<b>(3,156,107)</b>	<b>(1,468,127)</b>	<b>(4,583,074)</b>	<b>(2,369,020)</b>
Income tax benefit	920,000	-	920,000	-
<b>NET LOSS</b>	<b>\$ (2,236,107)</b>	<b>\$ (1,468,127)</b>	<b>\$ (3,663,074)</b>	<b>\$ (2,369,020)</b>
<b>Loss per common share - basic and diluted</b>	<b>\$ (0.36)</b>	<b>\$ (0.33)</b>	<b>\$ (0.69)</b>	<b>\$ (0.54)</b>
<b>Weighted average shares of common shares - basic and diluted</b>	<b>6,157,970</b>	<b>4,383,433</b>	<b>5,275,603</b>	<b>4,383,433</b>

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Preferred Stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2016	-	\$ -	4,383,433	\$ 4,383	\$49,661,802	\$(51,985,517)	\$ (2,319,332)
Stock-based compensation expense					391,270		391,270
Conversion of convertible debt			250,681	251	3,119,287		3,119,538
Effect of reverse merger			1,403,271	1,403	15,047,480		15,048,883
Offering of common stock and warrants			2,646,091	2,646	2,122,657		2,125,303
Common shares issued to vendor			2,534	3	14,997		15,000
Net loss						(3,663,074)	(3,663,074)
Balance at June 30, 2017	-	\$ -	8,686,010	\$ 8,686	\$70,357,493	\$(55,648,591)	\$ 14,717,588

See accompanying notes to unaudited consolidated financial statements.

PLx Pharma Inc.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOW

	Six Months Ended June 30,	
	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (3,663,074)	\$ (2,369,020)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3,161	2,486
Share-based compensation	406,270	1,232,477
Noncash interest expense - beneficial conversion feature	623,908	-
Change in fair value of warrant liability	(1,746,420)	-
Expenses allocated to warrant liability	1,302,995	-
Deferred tax benefit	(920,000)	-
Changes in operating assets and liabilities:		
Accounts receivable	(375,951)	(25,649)
Inventory	(278,014)	(116,726)
Contract manufacturing deposit	(657,400)	-
Prepaid expenses	(271,623)	13,794
Accounts payable and accrued liabilities	(456,321)	94,373
Accrued interest	85,909	22,167
Accrued interest - related parties	13,747	11,874
Net cash used in operating activities	(5,932,813)	(1,134,224)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(90,513)	-
Cash received in business combination	11,776,427	-
Net cash provided by investing activities	11,685,914	-
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of convertible notes payable	460,000	972,700
Proceeds from issuance of convertible notes payable - related parties	108,300	455,000
Proceeds from Dipexium note	2,000,000	-
Proceeds from equity offering, net of allocated issuance costs	16,698,854	-
Net cash provided by financing activities	19,267,154	1,427,700
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>		
	25,020,255	293,476
Cash and cash equivalents, beginning of period	59,335	91,657
Cash and cash equivalents, end of period	\$ 25,079,590	\$ 385,133
<b>SUPPLEMENTAL INFORMATION</b>		
Cash paid during the period for:		
Income taxes	\$ -	\$ -
Interest	\$ -	\$ -
<b>NON-CASH FINANCING TRANSACTIONS</b>		
Issuance of common shares for business combination	\$ 15,048,883	\$ -
Issuance of common shares upon conversion of debt and accrued interest	\$ 2,495,620	\$ -

See accompanying notes to unaudited consolidated financial statements.

**PLx Pharma Inc.**  
**NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS**  
**JUNE, 30 2017**

**NOTE 1. BACKGROUND AND ORGANIZATION**

**Business Operations**

PLx Pharma Inc., together with its subsidiaries PLx Opco Inc. and PLx Chile SpA, is a late stage startup specialty pharmaceutical company focusing initially on commercializing two patent-protected lead products: Aspertec™ 325 mg and Aspertec™ 81 mg (referred to together as “Aspertec”). Aspertec 325 mg is approved by the U.S. Food and Drug Administration (“FDA”) for over-the-counter distribution and is the first ever liquid fill aspirin capsule.

PLx Chile SpA was formed on September 12, 2011 as a wholly-owned subsidiary of PLx Opco.

**Organization, Reincorporation, and Merger with Dipexium Pharmaceuticals, Inc.**

PLx Opco Inc., which was known as PLx Pharma Inc. immediately prior to the Merger described below, was originally incorporated in the State of Texas on November 12, 2002 under the name of ZT MediTech, Inc. (“ZTM”). In December 2002, ZTM changed its name to GrassRoots Pharmaceuticals, Inc. (“GrassRoots”). Business commenced upon initial capitalization on December 4, 2002. In March 2003, GrassRoots changed its name to PLx Pharma Inc. (“PLx Texas”).

On December 31, 2013, PLx Texas converted pursuant to a Plan of Conversion from a Texas corporation to a Texas limited liability company and changed its name to PLx Pharma LLC (“PLx LLC”). Concurrently, PLx LLC changed its tax structure for U.S. federal and state income tax from a C Corporation to a partnership, and adopted a new Limited Liability Company Agreement for operations of the entity. Pursuant to the conversion, shares of common and preferred stock of PLx Texas were exchanged for an equivalent number of common and preferred member units in PLx LLC. The various classes of preferred stock and their associated rights, principally relating to distributions and liquidation values but excluding conversion features, were retained in each of the preferred member units in the exchange.

On July 21, 2015, PLx LLC’s members voted to approve a Plan of Conversion whereby PLx LLC re-incorporated into a Delaware corporation, PLx Pharma Inc. (“Old PLx” and such conversion, the “Reincorporation”) effective July 27, 2015. In conjunction with the Reincorporation, each Preferred Unit was converted on a one for two-sevenths basis into 5,013,690 shares of common stock. Additionally, each Common Unit was converted on a one for one-fourteenth basis into 302,937 shares of common stock. In connection with the Reincorporation, the \$800,000 of notes executed in early 2015 plus accrued interest of \$53,187 and the 1,313,840 Incentive Units issued in conjunction with the notes were exchanged for 249,196 shares of common stock. The note exchange was accounted for as an extinguishment of debt with the fair market value of the common stock issued treated as an increase to common equity and an associated loss on extinguishment of debt of \$1,588,937 recorded in July 2015. Finally, all the remaining Incentive Units outstanding were cancelled in conjunction with the Reincorporation.

On December 22, 2016, Old PLx entered into an Agreement and Plan of Merger and Reorganization among Old PLx, Dipexium Pharmaceuticals, Inc. (“Dipexium”) and Dipexium AcquireCo. (the “Merger”). The Merger closed on April 19, 2017. Pursuant to the terms of the Merger and after the consummation of the Merger, Old PLx was renamed PLx Opco Inc. and became a wholly-owned subsidiary of Dipexium, and Dipexium was renamed PLx Pharma Inc. and became the continuing registrant and reporting company. Immediately after the Merger, Old PLx’s former shareholders owned a majority of the voting common stock of the combined company and controlled the combined company’s board of directors, and Old PLx’s officers became the officers of the combined company. The combined company, renamed as PLx Pharma Inc., together with its subsidiaries PLx Opco Inc. and PLx Chile SpA, is referred to herein as the “Company.” The Merger was accounted for as a reverse acquisition business combination and Old PLx’s historical consolidated financial statements have replaced Dipexium’s historical consolidated financial statements with respect to periods prior to the completion of the Merger. See Note 4. Unless otherwise indicated, with respect to any period of time prior to the completion of the Merger, references to the “Company,” “we,” “our” or “us” refer to Old PLx and not Dipexium.

**NOTE 2. LIQUIDITY AND GOING CONCERN**

The accompanying unaudited consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations and potential other funding sources, in addition to cash on hand, to meet our obligations as they become due. Based on the operating cash requirements and capital expenditures expected for 2017, the Company’s cash on hand at June 30, 2017, including the cash resources obtained in the Merger and from the equity financing completed in June 2017, is adequate to fund operations for at least twelve months from the date that these financial statements were issued. However, we expect we will need to raise substantial additional funding in the future to fund our future operations.

### **NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### **Basis of Accounting and Principles of Consolidation**

The accompanying interim consolidated financial statements are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) for interim financial information. Accordingly, they do not include all the information and footnotes required by U.S. Generally Accepted Accounting Principles (“GAAP”) for complete financial statements. These unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes for the year ended December 31, 2016 previously filed with the SEC on a current report on Form 8-K dated May 5, 2017. In the opinion of management, the unaudited interim consolidated financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company’s financial position as of June 30, 2017 and the results of operations for the three and six months ended June 30, 2017 and 2016. The interim consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2016 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

The accompanying consolidated financial statements include the accounts of PLx Pharma Inc. and its direct and indirect wholly-owned subsidiaries, PLx Opc Inc. and PLx Chile SpA. All significant intercompany balances and transactions have been eliminated within the consolidated financial statements. The Company operates in one business segment.

#### **Use of 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 amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, determining the fair value of tangible and intangible assets and liabilities acquired in business combinations, equity-based compensation, our allowance for inventory obsolescence, our allowance for doubtful accounts, contingent liabilities, fair value and depreciable lives of long-lived assets, and deferred taxes and the associated valuation allowance. Actual results could differ from those estimates.

#### **Foreign Currency**

The functional currency of PLx Chile SpA has been designated as the U.S. dollar. Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss. Unless otherwise noted, all references to “\$” or “dollar” refer to the U.S. dollar.

#### **Cash and Cash Equivalents**

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company maintains cash and cash equivalents in a financial institution that at times exceeds federally insured limits. Management believes that the Company’s credit risk exposure is mitigated by the financial strength of the banking institution in which the deposits are held. As of June 30, 2017, the Company had a cash and cash equivalents balance of approximately \$24.8 million in U.S. bank accounts that was not insured by the Federal Deposit Insurance Corporation.

#### **Allowance for Accounts Receivable**

An allowance for uncollectible accounts receivable is estimated based on historical experience, credit quality, age of the accounts receivable balances, and economic conditions that may affect a customer’s ability to pay. The allowance for uncollectible accounts receivable was zero as of June 30, 2017 and December 31, 2016, respectively.

#### **Inventory**

Inventory is stated at the lower of cost or net realizable value, using the average cost method. Inventory as of June 30, 2017 and December 31, 2016 was comprised of raw materials for the manufacture of Aspertec. The Company regularly reviews inventory quantities on hand and assesses the need for an allowance for obsolescence. The allowance for obsolete inventory was zero as of June 30, 2017 and December 31, 2016, respectively.

#### **Fair Value of Financial Instruments**

All financial instruments classified as current assets and liabilities are carried at cost, which approximates fair value, because of the short-term maturities of those instruments. For disclosures concerning fair value measurements, see Note 8.

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation. The Company capitalizes additions that have a tangible future economic life. Maintenance and repairs that do not improve or extend the lives of property and equipment are charged to operations as incurred. Depreciation expense is computed using the straight-line method over the estimated useful lives of each class of depreciable assets. Management reviews property and equipment for possible impairment whenever events or circumstances indicate the carrying amount of an asset may not be recoverable. If there is an indication of impairment, management prepares an estimate of future cash flows (undiscounted and without interest charges) expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value.

**Intangible Assets and Goodwill**

Intangible assets were acquired as part of the Merger and consist of definite-lived trademarks with an estimated useful life of seven years, an indefinite-lived intangible asset for acquired in-process research and development ("IPR&D") and goodwill (see Note 4).

Management evaluates indefinite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable, and at least on an annual basis on October 31 of each year, by comparing the fair value of the asset with its carrying amount. If the carrying amount of the intangible asset exceeds its fair value, an impairment loss would be recognized in the amount of such excess.

Goodwill is not amortized, but is subject to periodic review for impairment. Goodwill is reviewed annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Management performs its review of goodwill on its one reporting unit.

As described further below in this Note 3, the Company adopted Accounting Standards Update 2017-04, Intangibles-Goodwill and Other - Simplifying the Test for Goodwill Impairment, effective January 1, 2017. The adoption resulted in an update to the Company's accounting policy for goodwill impairment. The Company performs a one-step test in its evaluation of the carrying value of goodwill, if qualitative factors determine it is necessary to complete a goodwill impairment test. In the evaluation, the fair value of the relevant reporting unit is determined and compared to the carrying value. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable, and no further action is required. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying amount exceeds the reporting unit's fair value; and a charge is reported in impairment of goodwill in our consolidated statements of operations.

**Revenue Recognition**

The Company recognizes revenues when persuasive evidence of an arrangement exists, delivery has occurred or services have been provided, the purchase price is fixed or determinable and collectability is reasonably assured.

The Company generally receives cost reimbursement-based federal grants. For these grants, revenues are based on internal and subcontractor costs incurred that are specifically covered under reimbursement arrangements, and where applicable, an additional facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized as grant-related expenses are incurred by the Company or its subcontractors. The grant agreements with federal government agencies generally provide that, upon completion of a technology development program, the funding agency is granted a royalty-free license to use any technology developed during the course of the program for its own purposes, but not any preexisting technology that the Company used in connection with the program. The Company retains all other rights to use, develop, and commercialize the technology.

Joint development revenue is recognized when the related expenditure is made under the reimbursement provisions of the sponsored research agreement or activities under a patent license agreement. License revenue is recognized on a straight-line basis during the license period.

**Research and Development Expenses**

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of direct and indirect costs associated with specific projects and include fees paid to various entities that perform research related services for the Company.

**Stock-Based Compensation**

The Company recognizes expense in our consolidated statements of operations for the fair value of all stock-based compensation to key employees, nonemployee directors and advisors in the form of stock options and incentive units. The Company uses the Black-Scholes option valuation model to estimate the fair value of these awards on the grant date. Compensation cost is amortized on a straight-line basis over the vesting period for each respective award. The Company adopted new accounting guidance, effective January 1, 2017 with respect to stock-based compensation and related income tax aspects, and now accounts for forfeitures as they occur rather than using an estimated forfeiture rate. The adoption did not have a material impact on the consolidated financial statements.

**Income Taxes**

Taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

Tax benefits are initially recognized in the financial statements when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

Effective December 31, 2013 and prior to the Reincorporation, the Company, with the consent of its members, elected to be taxed as a partnership under the Internal Revenue Code. In lieu of corporate income taxes, the Company's members were taxed on their proportionate share of the Company's taxable income. As of the effective date of the partnership election and prior to the Reincorporation, future taxable income or deductions arising from differences between financial and tax bases of the Company's assets and liabilities were recognized in the tax returns of the individual members; as such, any deferred income taxes prior to the partnership election recorded by the Company were eliminated on December 31, 2013. The Company has determined that it is unlikely that any tax will arise from "built-in gains" and, accordingly, no provision has been made for any income tax liability associated with "built-in gains" at the date of the partnership election.

Prior to December 31, 2013, the Company filed income tax returns in the U.S. Federal jurisdiction and the state of Texas. The Company is subject to the Texas franchise tax, commonly referred to as the Texas margin tax. The Texas margin tax has been determined to be an income tax for accounting purposes. The computation of the tax liability is based on Company revenues reduced by certain deductions. Management has determined this tax to be immaterial and, accordingly, there is no provision for state income tax included in the accompanying consolidated financial statements.

The Company is no longer subject to U.S. Federal or state examinations by tax authorities for years before 2011.

#### **Reverse Stock Split**

The Board of Directors approved a 1-for-8 reverse stock split of the Company's common stock effective April 19, 2017. Stockholders' equity and all references to share and per share amounts in the accompanying consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

#### **Loss per share**

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method, and convertible notes using the if-converted method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) prior to the Merger closing in April 2017, convertible notes exercisable for or exchangeable into common stock, which have been excluded from the computation of diluted loss per share, was 3,575,928 shares and 691,374 shares as of June 30, 2017 and 2016, respectively.

#### **Recent Accounting Developments**

##### *Recently Adopted Guidance*

In August 2014, the Financial Accounting Standards Board ("FASB") issued guidance for the disclosure of uncertainties about an entity's ability to continue as a going concern. Under U.S. GAAP, continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Previously, there was no guidance in U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. This was issued by the FASB to provide guidance in U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, the guidance and related amendments to U.S. GAAP should reduce diversity in the timing and content of footnote disclosures. The amendments in this FASB update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company adopted this pronouncement effective for the year ended December 31, 2016; the adoption did not have a material impact to the consolidated financial statements.

In March 2016, the FASB issued guidance simplifying the accounting for, and financial statement disclosure of, stock-based compensation awards. Under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement, and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. Under the guidance, companies can also elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. The guidance is effective for reporting periods beginning after December 15, 2016, and early adoption is permitted, though all amendments to U.S. GAAP in the guidance must be adopted in the same period. The adoption of certain amendments in the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. The Company adopted this guidance effective January 1, 2017 and elected to account for forfeitures as they occur. The adoption did not have a material impact on the consolidated financial statements.

In July 2015, the FASB issued guidance for the accounting for inventory. One of the main provisions of this guidance update is that an entity should measure inventory within the scope of this update at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other guidance in Topic 330 to more clearly articulate the requirements for the measurement and disclosure of inventory. The amendments to U.S. GAAP in this update for public business entities are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company adopted this guidance effective January 1, 2017 and it did not have a material impact on the consolidated financial statements.

In November 2015, the FASB issued accounting guidance to simplify the presentation of deferred taxes. Previously, U.S. GAAP required an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts. Under this guidance, deferred tax liabilities and assets will be classified as noncurrent amounts. The standard is effective for reporting periods beginning after December 15, 2016. The Company adopted this guidance effective January 1, 2017 and it did not have a material impact on the consolidated financial statements.

In January 2017, the FASB issued accounting guidance simplifying the test for goodwill impairment. The new guidance eliminates Step 2 from the goodwill impairment test. An entity no longer will determine goodwill impairment by calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. This update is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this standard effective April 1, 2017, and its updated accounting policy for goodwill impairment is described above in this Note 3. While the adoption of this accounting guidance may have a material impact in determining the results of future goodwill impairment tests and therefore impact the consolidated financial statements, there was no impact of the adoption during the six months ended June 30, 2017.

#### *Unadopted Guidance*

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements. Because the Company does not have existing significant revenue arrangements, management believes the impact of adoption will not be material to its consolidated financial statements.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet, and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018, and early adoption is permitted. The guidance must be adopted on a modified retrospective basis, and provides for certain practical expedients. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

In June 2016, the FASB issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted for fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. The guidance is effective for fiscal years beginning after December 15, 2017. Early adoption is permitted. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying consolidated financial statements.

**NOTE 4. REVERSE MERGER BUSINESS COMBINATION**

On December 22, 2016, the Company entered into an Agreement and Plan of Merger and Reorganization among Old PLx, Dipexium and Dipexium AcquireCo. The Merger closed on April 19, 2017. Pursuant to the terms of the Merger and after the consummation of the Merger, Old PLx was renamed PLx Opco Inc. and became a wholly-owned subsidiary of Dipexium, and Dipexium (renamed PLx Pharma Inc.) became the continuing registrant and reporting company. Immediately after the Merger, Old PLx’s former shareholders owned a majority of the voting common stock of the combined company and controlled the combined company’s board of directors, and Old PLx’s officers became the officers of the combined company. The combined company, renamed as PLx Pharma Inc., together with its subsidiaries PLx Opco Inc. and PLx Chile SpA, is referred to herein as the “Company.” The business purposes of the Merger included, among other purposes, obtaining the following potential advantages: (i) the combined organization’s resources would be immediately available to allow commencement of manufacturing and pre-commercialization activities for Aspertec; and (ii) the public company status of Dipexium would allow the Company greater potential access to additional capital.

The Company accounted for the Merger as a reverse merger business combination using the purchase method of accounting. Because the Merger qualifies as a reverse acquisition and given that Old PLx was a private company at the time of the Merger and therefore its value was not readily determinable, the fair value of the merger consideration was deemed to be equal to the quoted market capitalization of Dipexium at the Merger date, reduced by the effective settlement of pre-existing debt between Old PLx and Dipexium. Total purchase consideration is as follows:

Dipexium market capitalization at closing	\$ 15,048,883
Effective settlement of pre-existing debt	<u>(2,045,151)</u>
Total purchase consideration	<u>\$ 13,003,732</u>

The Company recorded all tangible and intangible assets acquired and liabilities assumed at their preliminary estimated fair values on the Merger date. The following represents the allocation of the estimated purchase consideration:

Fair value of purchase consideration	\$ 13,003,732
Fair value of tangible assets acquired:	
Cash	\$ 11,776,427
Prepaid expenses	139,648
Fair value of identifiable intangible assets acquired:	
Trademarks	100,000
In-process research and development	2,200,000
Goodwill	2,061,022
Deferred tax liabilities, net	(920,000)
Accrued severance	(2,284,000)
Fair value of liabilities assumed	(69,365)
	<u>\$ 13,003,732</u>

The estimated fair value of the acquired trademarks was determined using a cost approach. The estimated fair value of the acquired in-process research and development was determined using an income approach.

The Company is in the process of obtaining input from third-parties of its tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed; thus the provisional measurements of intangibles, and liabilities assumed are subject to change, which could be significant. The Company will finalize the amounts recognized as it obtains the information necessary to complete the analysis. The Company expects to finalize these amounts as soon as possible but no later than one year from the acquisition date.

The Company received carryover tax basis in the acquired assets and liabilities and no tax basis in the intangible assets (including goodwill) established on the Merger date. Goodwill, primarily related to expected synergies gained from combining operations, sales growth from future product offerings and customers, together with certain intangible assets that do not qualify for separate recognition, including assembled workforce, is not tax deductible. The Company anticipates that the deferred tax liability associated with the book/tax basis difference in the acquired IPR&D is expected to reverse prior to the expiration of its other tax attributes. The Company recognized deferred tax liabilities of \$920,000 related to the book/tax basis differences in the acquired intangible assets. This acquired net deferred tax liability in the U.S. taxing jurisdiction resulted in an income tax benefit related to a reduction in the Company's previously established valuation allowance (which reduction is accounted for outside of purchase accounting).

#### Pro forma disclosures

The following unaudited pro forma financial information summarizes the results of operations for the six months ended June 30, 2017 and 2016 as if the Merger had been completed as of January 1, 2016. Pro forma information primarily reflects adjustments relating to (i) conversion of convertible notes and elimination of associated interest expense and (ii) the amortization of intangibles acquired. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition occurred as of January 1, 2016 or that may be obtained in the future.

Unaudited pro forma results	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Revenues	\$ 375,951	\$ 20,000
Net loss	\$ (5,096,845)	\$ (13,567,112)
Net loss per share	\$ (0.81)	\$ (2.25)

#### NOTE 5. DEBT

##### Convertible Notes Payable and Convertible Notes Payable – Related Parties

During 2016 and the six months ended June 30, 2017, the Company borrowed \$2,346,000 from 37 different lenders in increments ranging from \$5,000 to \$250,000, including \$588,300 from related parties. All notes accrued interest at 8% per annum with a maturity date of May 31, 2017. The notes provided for the conversion of principal and accrued interest at a fixed conversion price of \$7.84 per share immediately prior to the Merger. The notes plus accrued interest converted into 250,681 shares of common stock of Old PLx immediately prior to the Merger. The Company recognized interest expense of \$623,908 upon conversion relating to a contingent beneficial conversion feature.

## Note Payable

On January 6, 2017, and pursuant to the Merger agreement with Dipexium, the Company borrowed \$2 million from Dipexium. The loan accrued interest on all outstanding principal at a rate of 8% per annum and had a maturity date that is the later of (a) October 15, 2017, or (b) the date that is 270 days following the termination of the Merger Agreement, subject to acceleration in the event that (i) the Merger Agreement is terminated by Dipexium under certain conditions. The loan was secured by a first priority perfected security interest in, and lien on, all right, title and interest of Old PLx in and to substantially all of its assets. Upon the occurrence of certain events that would have resulted in a termination of the Merger agreement, any security interest created by the promissory note would have ceased to be effective. However, as the Merger closed on April 19, 2017, those provisions are no longer applicable and the applicable security interest has been terminated. The note payable and related accrued interest were effectively settled with the Merger (see Note 4) and subsequent to the Merger closing are eliminated in consolidation.

Total interest expense for the six months ended June 30, 2017 and 2016 was \$723,563 and \$34,041, respectively. Total interest expense for the three months ended June 30, 2017 and 2016 was \$642,006 and \$24,608, respectively.

## NOTE 6. STOCKHOLDERS' EQUITY

### Equity Financing

On June 14, 2017, the Company completed a concurrent public offering of common stock and private placement of stock purchase warrants to investors, issuing (i) 2,646,091 shares of common stock in the public offering at \$6.875 per share and (ii) stock purchase warrants to purchase 2,646,091 shares of common stock at an exercise price of \$7.50 per share in the private placement, generating total gross proceeds of approximately \$18.2 million. The warrants, exercisable beginning six months and one day after issuance, have a 10 year term and are recognized as a liability due to certain cash settlement provisions.

### Stock Options

Following is a summary of option activities for the six months ended June 30, 2017:

	Number of Units	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2016	691,374	\$ 12.44	8.62	-
Granted	46,500	7.94		
Options from Dipexium	191,963	57.94		
Cancelled	-			
Outstanding, June 30, 2017	<u>929,837</u>	21.61	7.89	135
Exercisable, June 30, 2017	<u>743,486</u>	24.19	7.71	-

The Company grants options to employees, directors, advisors, and consultants from two current plans – the Old PLx Omnibus Stock Option Plan and the Dipexium 2013 Equity Incentive Plan. On April 19, 2017, the Company completed the Merger with Dipexium and Dipexium had 191,963 fully vested options outstanding as of the merger closing date that will continue to be exercisable. At June 30, 2017, an aggregate of 479,775 shares of common stock remained available for grant under the two plans.

On May 12, 2016, the Company modified certain options previously issued to its executives. After the modification, options to purchase 118,134 common shares originally vesting on the closing date of an initial public offering instead vested on July 22, 2016. The modified options had an aggregate fair value of \$948,117, which was calculated using the Black-Scholes model on the modification day. Variables used in the Black-Scholes model include: (1) discount rate of 1.24%; (2) expected life of 4.69 years; (3) expected volatility of 83.52%, and (4) zero expected dividends. The Company amortized the entire value during the second and third quarters of 2016.

During the second quarter 2017, the Company granted total options of 46,500 to two employees at a weighted average strike price of \$7.94 per share with a term of 10 years and vesting over 3 years. The options had an aggregate fair value of approximately \$267,000, which was calculated using the Black-Scholes model on the grant date. Variables used in the Black-Scholes model include: (1) discount rate of 1.99%; (2) expected life of 6 years; (3) expected volatility of approximately 86%, and (4) zero expected dividends.

As of June 30, 2017, the Company had \$1,258,692 in unamortized expense related to unvested options which is expected to be expensed over a weighted average of 1.75 years.

During the six months ended June 30, 2017 and 2016, the Company recorded \$391,270 and \$1,232,477, respectively, in compensation expense related to the stock options. During the three months ended June 30, 2017 and 2016, the Company recorded \$203,361 and \$912,047, respectively, in compensation expense related to the stock options. All stock-based compensation expense is classified as general and administrative expenses in the accompanying consolidated statements of operations.

## NOTE 7. COMMITMENTS AND CONTINGENCIES

### Lease Agreement

The Company presently leases office space under operating lease agreements, expiring on December 31, 2017 and July 31, 2021, respectively. The office leases require the Company to pay for its portion of taxes, maintenance and insurance. Rental expense under these agreements was \$60,363 and \$34,434 for the six months ended June 30, 2017 and 2016, respectively, and was \$49,392 and \$20,477 for the three months ended June 30, 2017 and 2016, respectively.

Future minimum lease payments under non-cancelable operating leases with terms expiring in 2021 are:

2017	\$ 145,371
2018	238,243
2019	244,902
2020	251,761
2021	150,489
Total	<u>\$ 1,030,766</u>

**Patent License Agreement with the Board of Regents of the University of Texas (NSAIDs)**

On January 8, 2003, the Company entered into a patent license agreement with the Board of Regents of The University of Texas System, under which it acquired an exclusive license for several patents and patent applications both inside and outside of the United States relating to gastrointestinal safer formulations of nonsteroidal anti-inflammatory drugs (“NSAIDs”). Additionally, the Company acquired worldwide rights to commercialize licensed products which allow for the Company to grant sublicenses subject to royalty payments.

Under terms of the agreement, the Company is responsible for conducting clinical trials involving investigational use of a licensed product for the determination of metabolic and pharmacologic actions in humans, the side effects associated with increasing doses, examination of suspected indications, determination of the potential short-term side effects in humans and for establishing the safety, efficacy, labeled indications and risk-benefit profile in humans. The patent license agreement also requires the Company to provide reimbursement for all expenses incurred by The University of Texas Health Science Center at Houston for filing, prosecuting, enforcing and maintaining patent rights and requires an annual nonrefundable license management fee. In addition, the Company is obligated to pay certain milestone payments in future years relating to royalties resulting from the approval to sell licensed products and the resulting sales of such licensed products.

**Development and Commercialization Agreement with Lee’s Pharmaceutical Holdings Limited**

In March 2012, the Company entered into a development and commercialization license agreement with Lee’s Pharmaceutical Holdings Limited, Zhaoke Pharmaceutical (Heifei) Co. Ltd., and Zhaoke Pharmaceutical (Guangzhou) Co. Ltd. (collectively, “Lee’s Pharmaceutical”). The Company granted to Lee’s Pharmaceutical an exclusive royalty bearing license under licensed subject matter to commercialize marketed products using PL 2200 Aspirin technology within the People’s Republic of China.

On June 19, 2015, the Company and Lee’s Pharmaceutical entered into an amendment to the Development and Commercialization Agreement. Pursuant to the agreement, Lee’s Pharmaceutical paid the Company a \$200,000 non-refundable advance payment of royalties in July 2015, which is being deferred until minimum or commercial royalties are expected to begin. This amount is included as deferred revenue as of June 30, 2017 and December 31, 2016.

**Master Services Agreement with Pharmaceutical Manufacturing Research Services, Inc.**

In February 2017, the Company entered into a master services agreement with Pharmaceutical Manufacturing Research Services, Inc. (“PMRS”). Pursuant to the agreement, PMRS agreed to provide manufacturing and project management services related to Aspertec. The agreement has a term of five years and allows the Company and PMRS to contract multiple projects. The initial two projects are estimated to cost \$2.1 million. In February 2017 and June 2017, the Company paid a total of \$912,500 as two deposits for project initiation. As of June 30, 2017, the remaining unused deposit was \$657,400.

**Investor Relations Agreement**

On March 21, 2017, the Company entered into an agreement with an investor relations firm. The agreement has a term of 15 months and the Company agreed to pay a fee of \$11,250 in cash for the period from March 15, 2017 through April 30, 2017 and a monthly fee of \$15,000 starting May 1, 2017. The \$15,000 monthly fee is \$7,500 payable in cash and \$7,500 payable in the Company’s common shares. The Company issued 2,534 common shares in the six months ended June 30, 2017 as payment for services for May and June, 2017. Subsequent to June 30, 2017, the Company issued 2,383 common shares as payment for services for July and August 2017 valued at \$15,000.

**NOTE 8. FAIR VALUE MEASUREMENTS**

Fair value is defined as the price that would be received in the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company has categorized all investments recorded at fair value based upon the level of judgment associated with the inputs used to measure their fair value.

Hierarchical levels, directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

- Level 1: Quoted prices in active markets for identical assets or liabilities that the organization has the ability to access at the reporting date.
- Level 2: Inputs other than quoted prices included in Level 1, which are either observable or that can be derived from or corroborated by observable data as of the reporting date.
- Level 3: Inputs include those that are significant to the fair value of the asset or liability and are generally less observable from objective resources and reflect the reporting entity’s assumptions about the assumptions market participants would use in pricing the asset or liability.

**Financial assets and liabilities measured at fair value on a recurring basis**

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

The stock purchase warrants issued in June 2017 contain certain cash settlement features and, accordingly, the Company considered them to be liabilities and accounted for them at fair value using level 3 inputs. The Company determined the fair value of this warrant liability using a binomial asset pricing model that consisted of a conditional probability weighted expected return method that values the Company's equity securities assuming various possible future outcomes to estimate the allocation of value within one or more of the scenarios. Using this method, unobservable inputs included the Company's equity value, the exercise price for the warrant, expected timing of possible outcomes, risk free interest rates and stock price volatility. The following table sets forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the six months ended June 30, 2017:

Description	Balance at December 31, 2016	Established in 2017	Change in Fair Value	Balance at June 30, 2017
Warrant liability	\$ -	\$ 15,876,546	\$ (1,746,420)	\$ 14,130,126

The following table identifies the carrying amounts of such assets and liabilities at June 30, 2017:

Liabilities	Level 1	Level 2	Level 3	Total
Warrant liability	\$ -	\$ -	\$ 14,130,126	\$ 14,130,126
Balance at June 30, 2017	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 14,130,126</u>	<u>\$ 14,130,126</u>

The Company had no financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2016.

#### Financial assets and liabilities carried at fair value on a non-recurring basis

The Company does not have any financial assets and liabilities measured at fair value on a non-recurring basis.

#### Non-financial assets and liabilities carried at fair value on a recurring basis

The Company does not have any non-financial assets and liabilities measured at fair value on a recurring basis.

#### Non-financial assets and liabilities carried at fair value on a non-recurring basis

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when they are deemed to be impaired. No such impairment was recognized in the six and three months ended June 30, 2017 and 2016.

See Note 4 for a discussion of the fair value of assets acquired and liabilities assumed in the Merger.

### NOTE 9. SUBSEQUENT EVENTS

On July 1, 2017, the Company granted options to purchase 60,000 shares of common stock to its Chief Financial Officer at an exercise price of \$6.28 per share. The options have a term of 10 years and vest in equal amounts on each of the first three anniversaries of the grant date.

Effective July 31, 2017, the Company entered into a separation agreement with its former Acting Chief Financial Officer. Pursuant to the agreement, the Company agreed to pay monthly severance payment of \$12,500 for twelve months following the separation date.

On August 9, 2017, the Company entered a Loan and Security Agreement with Silicon Valley Bank ("SVB") that provides for a Term Loan Facility (the "Term Loan Facility" and all amounts borrowed thereunder, the "Term Loan"). Under the Term Loan Facility, the Company borrowed an initial amount of \$7.5 million, and will have the right to borrow an additional \$7.5 million on or before December 31, 2018, provided that the Company first obtains (a) net new capital of not less than \$20,000,000 and (ii) FDA approval for the 81 mg formulation of Aspertec, the Company's lead product.

The Term Loan Facility carries interest at a floating rate of 4.0% above the prime rate per annum, with interest payable monthly. The monthly payments will consist of interest-only for the first 18 months, after which the Term Loans will be payable in 24 equal monthly installments of principal, plus accrued interest. All outstanding principal and accrued and unpaid interest under the Term Loan will be due and payable on February 1, 2021. Once repaid, the Term Loan may not be reborrowed.

The Company may elect to prepay the Term Loan Facility prior to the maturity date subject to a prepayment fee equal to 3.0% of the then outstanding principal balance if the prepayment occurs within one year of the funding date, 2.0% of the then outstanding principal balance if the prepayment occurs during the second year following the funding date, and 1.0% of the then outstanding principal balance if the prepayment occurs after the second anniversary of the funding date. The Term Loan Facility includes a final payment fee equal to 8.0% of the term loan commitment.

The Term Loan Facility is collateralized by substantially all of the Company's assets, including the Company's intellectual property. The Term Loan Facility also contains certain restrictive covenants that limit the Company's ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions, as well as financial reporting requirements. The Term Loan Facility contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on the lenders' security interest over the collateral, and a material adverse change. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company would begin to bear interest at a rate that is 5.00% above the rate effective immediately before the event of default, and may be declared immediately due and payable by SVB.

In connection with entry into the Term Loan Facility, the Company issued to SVB and one of its affiliates, warrants to purchase an aggregate of 58,502 shares of common stock of the Company at an exercise price of \$6.41 per share. The warrants are immediately exercisable, have a 10 year term, and also contain a cashless exercise provision.

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

*Statements in this Quarterly Report that are not strictly historical are forward-looking statements and include statements about products in development, results and analyses of pre-clinical studies, clinical trials and studies, research and development expenses, cash expenditures, and alliances and partnerships, among other matters. You can identify these forward-looking statements because they involve our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. These factors include, but are not limited to, risks relating to our ability to conduct and obtain successful results from ongoing clinical trials, commercialize our technology, obtain regulatory approval for our product candidates, contract with third parties to adequately test and manufacture our proposed therapeutic products, protect our intellectual property rights and obtain additional financing to continue our development efforts. Some of these factors are more fully discussed in the section of this Quarterly Report entitled "Risk Factors" and elsewhere herein. We do not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.*

We urge you to read this entire Quarterly Report on Form 10-Q, including the "Risk Factors" section, the financial statements, and related notes. As used in this Quarterly Report, unless the context otherwise requires, the words "we," "us," "our," "the Company" and "PLx Pharma" refers to PLx Pharma Inc. and its subsidiaries. The information contained herein is current as of the date of this Quarterly Report (June 30, 2017), unless another date is specified. We prepare our interim financial statements in accordance with U.S. GAAP. Our financials and results of operations for the three- and six-month periods ended June 30, 2017 are not necessarily indicative of our prospective financial condition and results of operations for the pending full fiscal year ending December 31, 2017. The interim financial statements presented in this Quarterly Report as well as other information relating to the Company contained in this Quarterly Report should be read in conjunction and together with the reports, statements and information filed by us with the United States Securities and Exchange Commission, or SEC.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is provided in addition to the accompanying financial statements and notes to assist readers in understanding our results of operations, financial condition and cash flows. Our MD&A is organized as follows:

- *Executive Overview* — Discussion of our business and overall analysis of financial and other highlights affecting the Company in order to provide context for the remainder of MD&A.
- *Trends & Outlook* — Discussion of what we view as the overall trends affecting our business and overall strategy.
- *Critical Accounting Policies* — Accounting policies that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.
- *Results of Operations* — Analysis of our financial results comparing the three- and six-month periods ended June 30, 2017 to the comparable periods of 2016.
- *Liquidity and Capital Resources* — An analysis of cash flows and discussion of our financial condition and future liquidity needs.

## Executive Overview

We are a late-stage specialty pharmaceutical company initially focused on developing our clinically validated and patent-protected PLxGuard delivery system to provide safer and more effective aspirin products. Our PLxGuard delivery system works by releasing active pharmaceutical ingredients into the duodenum, the first part of the small intestine immediately below the stomach, rather than in the stomach itself. We believe this improves the absorption of many drugs currently on the market or in development, and reduces acute gastrointestinal (GI) side effects — including erosions, ulcers and bleeding — associated with aspirin and ibuprofen, and potentially other drugs.

Our U.S. Food and Drug Administration, or FDA, approved lead product, Aspertec 325 mg, is a novel formulation of aspirin that uses the PLxGuard delivery system that is intended to significantly reduce acute GI side effects while providing superior antiplatelet effectiveness for cardiovascular disease prevention as compared with the current standard of care, enteric coated aspirin. Aspertec 325 mg (formerly PL2200 Aspirin 325 mg) was originally approved under the drug name aspirin, and the proprietary name 'Aspertec' was granted subsequent to the FDA approval. A companion 81 mg dose of the same novel formulation — Aspertec 81 mg — is in late-stage development and will be the subject of a supplemental New Drug Application, or sNDA, leveraging the already approved status of Aspertec 325 mg.

Our commercialization strategy will target both the over-the-counter, or OTC, and prescription markets, taking advantage of the existing OTC distribution channels for aspirin while leveraging the FDA approval of Aspertec 325 mg and expected approval for Aspertec 81 mg for OTC and prescription use when recommended by physicians for cardiovascular disease treatment and prevention. Given our clinical demonstration of better antiplatelet efficacy (as compared with enteric coated aspirin) and better acute GI safety, we intend to use a physician-directed sales force to inform physicians — and, by extension, consumers — about our product's clinical results in an effort to command both greater market share and a higher price for our superior aspirin product. Our product pipeline also includes other oral nonsteroidal anti-inflammatory drugs, or NSAIDs, using the PLxGuard delivery system that may be developed, including a clinical-stage, GI-safer ibuprofen — PL1200 Ibuprofen 200 mg — for pain and inflammation.

### *PLxGuard™ Delivery System*

Our PLxGuard delivery system uses surface acting lipids, such as phospholipids and free fatty acids, to modify the physiochemical properties of various drugs to selectively release these drugs to targeted portions of the GI tract. Unlike tablet or capsule polymer coating technologies (e.g., enteric coating), which rely solely on drug release based on pH differences in the GI tract, the PLxGuard delivery system uses the differential in pH and bile acid contents between the stomach and duodenum to target Aspertec's release. This approach is intended to more reliably release active pharmaceutical ingredients in the duodenum and decrease their exposure to the stomach, which is more susceptible to NSAID-induced bleeding and ulceration. The PLxGuard delivery system is a platform technology that we believe may be useful in improving the absorption of many acid labile, corrosive, and insoluble or impermeable drugs.

We believe our PLxGuard delivery system has the potential to improve many already-approved drugs and drugs in development because it may:

- enhance the efficacy of the drug using our technology;
- improve the GI safety of the drug;
- provide new or extended patent protection for an already-approved or development-stage drug; and
- utilize the 505(b)(2) New Drug Application, or NDA, regulatory path, which may provide a faster and lower-cost FDA approval route when used with already-approved drugs.

The PLxGuard delivery system has clinically proven these benefits with our novel formulations using aspirin and has clinical evidence supporting the potential for a GI-safer ibuprofen and preclinical evidence supporting the potential for a GI-safer oral diclofenac and intravenous indomethacin products. Other existing or new drugs in development that may benefit from the PLxGuard delivery system will be evaluated either by us or through collaboration agreements with other companies.

### *Product Pipeline*

Our lead product, Aspertec 325 mg, has been approved by the FDA for OTC distribution and is the first-ever FDA-approved liquid-fill aspirin capsule. All the clinical trials necessary for product launch have been completed. In clinical trials in diabetic patients at risk for cardiovascular disease, Aspertec 325 mg demonstrated better antiplatelet efficacy compared with enteric coated aspirin, which is the current standard of care for cardiovascular disease prevention and treatment. Aspertec 325 mg delivers faster antiplatelet efficacy than enteric coated aspirin with a median time to 99% inhibition of serum Thromboxane B2 of two hours compared with 48 hours for enteric coated aspirin. Serum Thromboxane B2 is a clinically accepted marker for antiplatelet efficacy, which is sometimes referred to as aspirin response.

Aspertec 325 mg provides more reliable, predictable and sustained antiplatelet benefits than enteric coated aspirin with a 3 – 5 times greater chance of a complete aspirin antiplatelet effect than enteric coated aspirin. Aspertec 325 mg has demonstrated a statistically significant 65% reduction in the risk of acute ulcers compared with immediate release aspirin in healthy subjects with an age associated risk for cardiovascular disease. This acute GI safety benefit may also be important for acute coronary syndrome, or ACS, patients. Moreover, we believe ACS patients who are also diabetics and suffer from gastroparesis, or a lack of digestive stomach motility, could also benefit from Aspertec due to its more predictable absorption when compared to enteric coated aspirin. The acute GI safety benefit may also be used to differentiate Aspertec 325 mg from products intended for use in conditions associated with pain and inflammation, including other aspirin and NSAID products.

Aspertec 81 mg is our lower-dose companion product for Aspertec 325 mg (the two dose forms are sometimes referred to in this report together as “Aspertec”). This product utilizes exactly the same formulation as the 325 mg product (except delivered in a capsule one quarter the size) and will be the subject of an sNDA, which we expect to submit to the FDA in late first quarter of 2018. We do not anticipate any additional regulatory clinical trials will be required, effectively positioning this product as an end of Phase 3 status. We intend to begin selling both products by the end of 2018.

We also believe our technology may be used with other selected NSAIDs, such as ibuprofen. We have used the PLxGuard delivery system to create a lipid-based formulation of ibuprofen, PL1200 Ibuprofen 200 mg, for the OTC market, and PL1100 Ibuprofen 400 mg, for prescription doses of ibuprofen. We have OTC and prescription (Rx) Investigational New Drug applications, or INDs, active with the FDA and have demonstrated bioequivalence with the OTC 200 mg dose ibuprofen to support a 505(b)(2) NDA in fasted-state clinical trials at three different doses, 200 mg, 400 mg and 800 mg. Using the PL1200 capsules at prescription doses, we demonstrated better GI safety in osteoarthritic patients with equivalent analgesic and anti-inflammatory efficacy, when compared with prescription ibuprofen in a six-week endoscopy pilot clinical trial. PL1200 and PL1100 Ibuprofen may be considered as being in Phase 1 in the FDA process and may qualify for the 505(b)(2) NDA path.

### **Employees**

As of July 31, 2017, we had nine (9) full-time employees. Of these full-time employees, three (3) work on research and development, manufacturing, and clinical operations and six (6) work in management and administration. We also use the services of numerous outside consultants in business and scientific matters.

### **Our Corporate Information**

We were originally incorporated in Texas in 2002 and re-incorporated in Delaware in 2015. Our principal executive offices are located at 8285 El Rio Street, Ste. 130, Houston, Texas 77054, and our telephone number is (713) 842-1249. Our website address is [www.plxpharma.com](http://www.plxpharma.com).

We have not incorporated by reference into this report the information in, or that can be accessed through, our website and you should not consider it to be a part of this report.

### **Critical Accounting Policies**

Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Note 3 of the Notes to Unaudited Consolidated Financial Statements included elsewhere herein describes the significant accounting policies used in the preparation of the financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (1) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (2) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

Estimates and assumptions about future events and their effects cannot be determined with certainty. We base our estimates on historical experience and on various other assumptions believed to be applicable and reasonable under the circumstances. These estimates may change as new events occur, as additional information is obtained and as our operating environment changes. These changes have historically been minor and have been included in the financial statements as soon as they became known. Based on a critical assessment of our accounting policies and the underlying judgments and uncertainties affecting the application of those policies, management believes that our financial statements are fairly stated in accordance with U.S. GAAP and present a meaningful presentation of our financial condition and results of operations. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our consolidated financial statements:

#### **Use of Estimates**

The preparation of financial statements in conformity with U.S. 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 amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, determining the fair value of tangible and intangible assets and liabilities acquired in business combinations, equity-based compensation, allowance for inventory obsolescence, allowance for doubtful accounts, contingent liabilities, fair value and depreciable lives of long-lived assets, and deferred taxes and associated valuation allowance. Actual results could differ from those estimates.

#### **Fair Value Measurements**

Fair value is defined as the price that would be received in the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company has categorized all investments recorded at fair value based upon the level of judgment associated with the inputs used to measure their fair value.

Hierarchical levels, directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

- Level 1: Quoted prices in active markets for identical assets or liabilities that the organization has the ability to access at the reporting date.
- Level 2: Inputs other than quoted prices included in Level 1, which are either observable or that can be derived from or corroborated by observable data as of the reporting date.
- Level 3: Inputs include those that are significant to the fair value of the asset or liability and are generally less observable from objective resources and reflect the reporting entity's assumptions about the assumptions market participants would use in pricing the asset or liability.

The Company's financial instruments (cash and cash equivalents, receivables, accounts payable and accrued liabilities) are carried in the consolidated balance sheet at cost, which reasonably approximates fair value based on their short-term nature. The Company's warrant liabilities are recorded at fair value, with changes in fair value being reflected in the statements of operations for the period of change.

#### **Research and Development Expenses**

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of direct and indirect costs associated with specific projects and include fees paid to various entities that perform research related services for the Company.

#### **Stock-Based Compensation**

The Company recognizes expense in the consolidated statements of operations for the fair value of all stock-based compensation to key employees, nonemployee directors and advisors in the form of stock options and incentive units. The Company uses the Black-Scholes option valuation model to estimate the fair value of these awards on the grant date. Compensation cost is amortized on a straight-line basis over the vesting period for each respective award. The Company adopted new accounting guidance, effective January 1, 2017 with respect to stock-based compensation and related income tax aspects, and now accounts for forfeitures as they occur rather than using an estimated forfeiture rate. The adoption did not have a material impact on the consolidated financial statements.

#### **Adopted Accounting Guidance**

The following discusses significant accounting recently adopted or unadopted accounting guidance that has the potential of being significant:

In January 2017, the FASB issued accounting guidance simplifying the test for goodwill impairment. The new guidance eliminates Step 2 from the goodwill impairment test. An entity no longer will determine goodwill impairment by calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. This update is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this standard effective April 1, 2017, and its updated accounting policy for goodwill impairment is described in Note 3. While the adoption of this accounting guidance may have a material impact in determining the results of future goodwill impairment tests and therefore impact the consolidated financial statements, there was no impact of the adoption during the six months ended June 30, 2017.

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements. Because the Company does not have existing significant revenue arrangements, management believes the impact of adoption will not be material to its consolidated financial statements.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet, and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018, and early adoption is permitted. The guidance must be adopted on a modified retrospective basis, and provides for certain practical expedients. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

In June 2016, the FASB issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted for fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact, if any, that this guidance will have on the consolidated financial statements.

## RESULTS OF OPERATIONS

### Comparison of Three Months Ended June 30, 2017 and 2016

#### *Revenue*

Total revenues increased approximately \$356,000 comparing revenues for the three months ended June 30, 2017 to the comparable period in 2016. The increase was largely attributable to approximately \$376,000 of federal grant revenue earned on the recent award of a NIH grant partially offset by the absence of \$20,000 of license income recognized in the prior year period.

#### *Operating Expenses*

Total operating expenses increased by approximately \$3.2 million from approximately \$4.7 million for the three months ended June 30, 2017 compared to approximately \$1.5 million in the comparable period in 2016.

Operating expenses for the three months ended June 30, 2017 and 2016 were as follows (rounded to nearest thousand):

	<b>Three Months Ended March 31,</b>		<b>Increase (Decrease)</b>	
	<b>2017</b>	<b>2016</b>	<b>\$</b>	<b>%</b>
<b>Operating Expenses</b>				
Research and development expenses	\$ 626,000	\$ 13,000	\$ 613,000	NMF
General and administrative expenses	4,025,000	1,451,000	2,574,000	177%
Total operating expenses	<u>\$ 4,651,000</u>	<u>\$ 1,464,000</u>	<u>\$ 3,187,000</u>	218%

#### *Research and Development Expenses*

Research and development expenses totaled approximately \$0.6 million in the three months ended June 30, 2017 compared to approximately \$13,000 in the prior year period, an increase of approximately \$613,000. The increase was attributable to the near absence of any research and development expenses in 2016 and the initiation of technology transfer, contract manufacturing activities, and other product development activities for Aspertec throughout the second quarter of 2017.

#### *General and Administrative Expenses*

General and administrative expenses totaled approximately \$4.0 million in the three months ended June 30, 2017 compared to approximately \$1.45 million in the prior year period, an increase of approximately \$2.6 million. The increase was primarily attributable to (i) increased compensation expense and outside directors fees totaling approximately \$1.2 million including one-time discretionary bonus compensation issued to senior management pursuant to employment agreements and the achievement of a threshold financing amount; (ii) public offering costs totaling approximately \$1.3 million expensed and attributable to the warrant liability issued in conjunction with the June 2017 equity offering; and (iii) other professional fees including legal, accounting, and financial advisory totaling approximately \$0.5 million which were partially offset by a decrease in stock-based compensation expenses of approximately \$0.7 million.

#### *Other income (expense), net*

Other income, net totaled approximately \$1.1 million in the three months ended June 30, 2017 compared to other expense, net of approximately \$24,000 in the prior year period. The increase is largely attributable to the change in fair value of warrant liability recorded as of June 30, 2017 of approximately \$1.7 million partially offset by approximately \$0.6 million of interest expense recognized upon conversion of convertible notes relating to a contingent beneficial conversion feature.

### **Comparison of Six Months Ended June 30, 2017 and 2016**

#### *Revenue*

Total revenues increased approximately \$356,000 comparing revenues for the six months ended June 30, 2017 to the comparable period in 2016. The increase was largely attributable to approximately \$376,000 of federal grant revenue earned on the recent award of a NIH grant partially offset by the absence of \$20,000 of license income recognized in the prior year period.

#### *Operating Expenses*

Total operating expenses increased by approximately \$3.6 million from approximately \$6.0 million in the six months ended June 30, 2017 compared to approximately \$2.4 million in the comparable period in 2016.

Operating expenses for the six months ended June 30, 2017 and 2016 were as follows (rounded to nearest thousand):

	<u>Six Months Ended June 30,</u>		<u>Increase (Decrease)</u>	
	<u>2017</u>	<u>2016</u>	<u>\$</u>	<u>%</u>
Operating Expenses				
Research and development expenses	\$ 755,000	\$ 53,000	\$ 702,000	NMF
General and administrative expenses	5,242,000	2,302,000	2,940,000	128%
Total operating expenses	<u>\$ 5,997,000</u>	<u>\$ 2,355,000</u>	<u>\$ 3,642,000</u>	155%

#### *Research and Development Expenses*

Research and development expenses totaled approximately \$0.8 million in the six months ended June 30, 2017 compared to approximately \$53,000 in the comparable period in 2016, an increase of approximately \$702,000. The increase was attributable to the nominal research and development expenses in the six months ended June 30, 2016 of approximately \$53,000 as compared to the initiation of technology transfer, contract manufacturing activities, and other product development activities for Aspertec beginning in March of 2017.

#### *General and Administrative Expenses*

General and administrative expenses totaled approximately \$5.2 million in the six months ended June 30, 2017 compared to approximately \$2.3 million in the prior year period, an increase of approximately \$2.9 million. The increase was primarily attributable to (i) increased compensation expense and outside directors fees including one-time discretionary bonus compensation issued to senior management pursuant to employment agreements and the achievement of a threshold financing amount totaling approximately \$1.6 million; (ii) public offering costs totaling approximately \$1.3 million expensed and attributable to the warrant liability issued in conjunction with the June 2017 equity offering; and (iii) other professional fees including legal, accounting, and financial advisory totaling approximately \$0.5 million which were partially offset by a decrease in stock-based compensation expenses of approximately \$0.8 million.

#### *Other income (expense), net*

Other income, net totaled approximately \$1.0 million in the six months ended June 30, 2017 compared to other expense, net of approximately \$34,000 in the prior year period. The increase is primarily attributable to the change in fair value of warrant liability recorded as of June 30, 2017 of approximately \$1.7 million partially offset by approximately \$0.7 million of interest expense including approximately \$0.6 million of interest expense recognized upon conversion of convertible notes relating to a contingent beneficial conversion feature.

### **Liquidity and Capital Resources**

#### **Financial Condition**

The following table summarizes the primary uses and sources of cash for the periods indicated:

(rounded to nearest thousand)	<u>Six Months Ended June 30,</u>		<u>Increase (Decrease)</u>	
	<u>2017</u>	<u>2016</u>	<u>\$</u>	<u>%</u>
Net cash used in operating activities	\$ (5,933,000)	\$ (1,134,000)	\$ (4,799,000)	(423%)
Net cash provided by investing activities	\$ 11,686,000	\$ -	\$ 11,686,000	NMF
Net cash provided by financing activities	\$ 19,267,000	\$ 1,428,000	\$ 17,839,000	NMF

#### *Net Cash Used in Operating Activities*

Cash used in operating activities of approximately \$5.9 million for the six months ended June 30, 2017 primarily reflects our net loss for the period of approximately \$3.7 million adjusted for (i) approximately \$1.7 million change in fair value of warrant liability reflected as other income, (ii) total operating asset/liability change of approximately \$2.0 million, (iii) approximately \$0.9 million deferred tax benefit resulting from the Merger partially offset by (iv) approximately \$1.3 million of offering expenses attributable to the warrant liability resulting from our June 2017 public offering, (v) approximately \$0.4 million of stock based compensation and (vi) approximately \$0.6 million of noncash interest expense relating to a beneficial conversion feature.

Cash used in operating activities of approximately \$1.1 million for the six months ended June 30, 2016 primarily reflects our net loss for the period of approximately \$2.4 million adjusted for approximately \$1.2 million of non-cash stock based compensation expense.

#### ***Net Cash Provided by Investing Activities***

Net cash provided by investing activities totaled approximately \$11.7 million in the six months ended June 30, 2017 while the comparable period in 2016 had no cash flows associated with the investing activities. In 2017, cash acquired from Dipexium in the Merger totaled approximately \$11.8 million and was partially offset by approximately \$0.1 million of equipment purchases.

#### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities totaled approximately \$19.3 million in the six months ended June 30, 2017 as compared to approximately \$1.4 million in the six months ended June 30, 2016. Financing activities in 2017 consisted of approximately \$16.7 million of equity offering proceeds, \$2.0 million received from note with Dipexium issued prior to the Merger, and approximately \$0.6 million of convertible note proceeds which subsequently converted to Old PLx equity immediately prior to the closing of the Merger. Financing activities in 2016 consisted solely of proceeds from the issuance of convertible notes.

#### ***Future Liquidity and Needs***

As of June 30, 2017, we had working capital of approximately \$24.1 million and cash and cash equivalents of approximately \$25.1 million. Based on the operating cash requirements and capital expenditures expected for 2017, the Company's cash on hand at June 30, 2017 is adequate to fund operations for at least twelve months from the date that this Quarterly Report on Form 10-Q was filed.

We have not generated any revenue from the sale of products, have generated minimal revenue from licensing activities, and have incurred losses in each year since we commenced operations. As of June 30, 2017, we had an accumulated deficit of approximately \$55.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and commercialization of Aspertec and our other product candidates. Even if we do generate revenues, we may never achieve profitability, and even if we do achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

We anticipate that we will need to raise substantial additional financing in the future to fund our future operations. We may obtain additional financing through public or private equity offerings, debt financings (including related-party financings), a credit facility or strategic collaborations. On August 9, 2017, we entered into a Loan and Security Agreement with Silicon Valley Bank that provides for a Term Loan Facility. Under the Term Loan Facility, the Company borrowed an initial amount of \$7.5 million, and will have the right to borrow an additional \$7.5 million on or before December 31, 2018, provided that the Company first obtains (a) net new capital of not less than \$20,000,000 and (ii) FDA approval for the 81 mg formulation of Aspertec, the Company's lead product.

Additional financing may not be available to us when we need it or it may not be available to us on favorable terms, if at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no understandings, commitments or agreements relating to any of these types of transactions. If we are unable to raise additional funds when needed, we may be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves. Without additional funding — or, alternatively, a partner willing to collaborate and fund development — we will be unable to continue development of PL1200 Ibuprofen or any other development-stage products in our pipeline.

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

We are not required to provide the information required by this item as we are considered a smaller reporting company, as defined by Rule 229.10(f)(1).

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

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

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on an evaluation under the supervision, and with the participation, of the Company's management, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of June 30, 2017 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control Over Financial Reporting**

As discussed above, pursuant to the terms of the Merger agreement and after the consummation of the Merger, Old PLx became a wholly-owned subsidiary of Dipexium, and Dipexium (renamed PLx Pharma Inc.) is the continuing registrant and reporting company, which is referred to herein, together with its subsidiaries PLx Opco Inc. and PLx Chile SpA, as the Company. The Merger has been accounted for as a reverse acquisition business combination. The registrant has not yet completed an assessment of the design and/or operating effectiveness of the Old PLx's internal control over

financial reporting. There were no other changes in the registrant's internal control over financial reporting during the quarter ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **Inherent Limitations Over Internal Controls**

The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. The Company's 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 the Company's assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that the Company's receipts and expenditures are being made only in accordance with authorizations of the Company's management and directors; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Management, including the Company's principal executive officer and principal financial officer, does not expect that the Company's internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, 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. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are parties to legal proceedings that we believe to be ordinary, routine litigation incidental to the business of present or former operations. It is management's opinion, based on the advice of counsel, that the ultimate resolution of such litigation will not have a material adverse effect on our financial condition, results of operations or cash flows.

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

*Investing in our common stock involves a high degree of risk. We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Quarterly Report, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report should be considered carefully in evaluating the Company and our business and the value of our securities.*

*Please also read carefully the section entitled "Information Regarding Forward-Looking Statements" included in this Quarterly Report.*

#### **Risks Related to Our Business and Capital Requirements**

*We have not yet generated significant revenues, have a limited operating history, have incurred net losses in each year since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.*

We have not generated any revenue from the sale of products, have generated minimal revenue from licensing activities, and have incurred losses in each year since we commenced operations. Old PLx's net loss for the year ended December 31, 2016 was \$4.9 million. Similarly, Dipexium incurred a net loss of \$21.3 million for the year ended December 31, 2016. As of June 30, 2017, we had an accumulated deficit of approximately \$55.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and commercialization of Aspertec and our other product candidates. Our expenses will also increase substantially if and when we:

- discover and develop additional product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize Aspertec and any other product candidates for which we may obtain marketing approval;
- establish a manufacturing and supply chain sufficient for commercial quantities of Aspertec and any other product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our obligations as a publicly reporting company; and
- acquire or in-license other product candidates and technologies.

Even if we do generate revenues, we may never achieve profitability, and even if we do achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

***We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate our operations or commercialization efforts.***

As of June 30, 2017, we had working capital of approximately \$24.1 million and cash and cash equivalents of approximately \$25.1 million. We anticipate that we will need to raise substantial additional financing in the future to fund our operations.

We may obtain additional financing through public or private equity offerings, debt financings (including related-party financings), a credit facility or strategic collaborations. Additional financing may not be available to us when we need it or it may not be available to us on favorable terms, if at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. Our future financing requirements will depend on many factors, some of which are beyond our control, including:

- our ability to enter into additional collaboration, licensing or other arrangements and the terms and timing of such arrangements;
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, including litigation costs and the results of such litigation;
- the emergence of competing technologies and other adverse market developments;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- our ability to enter into collaborative agreements to support the development of our product candidates and development efforts;
- the amount of funds we receive in this offering; and
- the costs associated with being a public company.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no understandings, commitments or agreements relating to any of these types of transactions. If we are unable to raise additional funds when needed, we may be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves. Without additional funding — or, alternatively, a partner willing to collaborate and fund development — we will be unable to continue development of PL1200 Ibuprofen or any other development-stage products in our pipeline.

***We are substantially dependent on the success of our lead product candidate, Aspertec. If we are unable to successfully commercialize Aspertec or experience significant delays in doing so, our business could be materially harmed.***

Our future success is substantially dependent on our ability to successfully commercialize Aspertec, which will depend on several factors, including the following:

- establishing commercial manufacturing and supply arrangements;
- establishing a commercial infrastructure;
- identifying and successfully establishing one or more collaborations to commercialize Aspertec;
- acceptance of the product by patients, the medical community and third-party payors;
- obtaining market share while competing with more established companies;
- a continued acceptable safety and adverse event profile of the product; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering the product.

***Serious adverse events, undesirable side effects or other unexpected properties of Aspertec or any other product candidate may be identified after approval that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.***

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, Aspertec or our other product candidates could cause us, an institutional review board, or regulatory authorities to interrupt, delay or halt our manufacturing and distribution operations and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If Aspertec or any of our other product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

Undesirable side effects or other unexpected adverse events or properties of Aspertec or any of our other product candidates could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our other product candidates. If such an event occurs with respect to Aspertec, a number of potentially significant negative consequences may result, including:

- regulatory authorities may withdraw the approval of such product;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- regulatory authorities may require one or more post-market studies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

***We may not be able to realize the anticipated benefits from combining the businesses of Dipexium and Old PLx.***

The Merger involved the integration of two companies that previously have operated independently with principal offices in two distinct locations. Significant management attention and resources have been and will be required to integrate the two companies. The failure to successfully integrate and manage successfully the challenges presented by the integration process may result in the combined organization's failure to achieve some or all of the anticipated benefits of the Merger.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined organization's cash and other assets efficiently to develop the business of the combined organization;
- appropriately managing the liabilities of the combined organization; and
- potential unknown or currently unquantifiable liabilities associated with the Merger and the operations of the combined organization.

Delays in the integration process could adversely affect our business, financial results, financial condition and stock price. Even if we are able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

***Even though Aspertec 325 mg has already obtained regulatory approval, it may never achieve market acceptance by physicians, patients, and others in the medical community necessary for commercial success and the market opportunity may be smaller than we estimate.***

Even if we are able to launch Aspertec commercially, it may not achieve market acceptance among physicians, patients, hospitals (including pharmacy directors) and third-party payors and, ultimately, may not be commercially successful. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidate as demonstrated in clinical trials;
- relative convenience and ease of administration;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- strength of competitive products;
- the effectiveness of our sales and marketing efforts;
- the strength of marketing and distribution support;
- the willingness of physicians to recommend or prescribe the product;
- the willingness of hospital pharmacy directors to purchase our products for their formularies;
- our ability to maintain regulatory approvals for Aspertec;
- acceptance by physicians, operators of hospitals and treatment facilities and parties responsible for reimbursement of the product;
- the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved risk evaluation and mitigation strategy;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products; and
- adverse publicity about the product or favorable publicity about competitive products.

For example, while we believe that the safety profile and certain efficacy data will allow us to differentiate Aspertec from other aspirin products in the market, we may not be able to make direct comparative claims regarding the safety or efficacy of Aspertec and other aspirin products in our promotional materials for Aspertec. Any failure by Aspertec or any other product candidate that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

***Our ability to market Aspertec for long-term use may be hampered by lack of trial results demonstrating long-term GI-safety benefits.***

While demonstrating a statistically significant reduction in mucosal damage at 42 days when evaluated using the same clinical endpoints used for early studies involving enteric coated aspirin, Aspertec 325 mg did not demonstrate a reduction in ulcer risk over the course of a 42-day trial when more contemporary clinical endpoints were used. This lack of demonstrated long-term GI benefits could hamper our ability to market Aspertec 325 mg for long-term use.

***For many new product candidates, we will rely on third parties to conduct our preclinical studies and all of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.***

If we elect to pursue new products, we will rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations, to conduct our preclinical studies and clinical trials on our product candidates in compliance with applicable regulatory requirements. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and the applicable legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices, or cGCPs, for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. If we or any of our third-party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, we are required to report certain financial interests of our third party investigators if these relationships exceed certain financial thresholds and meet other criteria. Our clinical trials must also generally be conducted with products produced under current good manufacturing practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Many of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations or comply with regulatory requirements we may need to enter into new arrangements with alternative third parties. This could be costly, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such studies or trials. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third party contractors or to do so on commercially reasonable terms. Though we carefully manage our relationships with our contract research organizations, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***Clinical trials for future products may be delayed or prevented.***

Clinical trials may be delayed or prevented for a broad range of reasons, including:

- Difficulties obtaining regulatory approval to begin trials;
- Delays in reaching agreements on acceptable terms with contract manufacturers and contract research organizations;
- Insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- Challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- Difficulties maintaining contact with subjects after treatment, which results in incomplete data;
- Receipt by a competitor of marketing approval for a product targeting an indication that our product targets, such that we are not “first to market” with our product candidate;
- Governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- Inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- Unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and
- Lack of adequate funding to continue the clinical trial.

One or more of these difficulties could result in delayed or cancelled trials and have a significant negative impact on our earnings.

***We will rely on third-party contract manufacturing organizations to manufacture and supply Aspertec and other product candidates for us, as well as certain raw materials used in the production thereof. If one of our suppliers or manufacturers fails to perform adequately we may be required to incur significant delays and costs to find new suppliers or manufacturers.***

We currently have limited experience in, and we do not own facilities for, manufacturing our product candidates, including Aspertec. We rely upon third-party manufacturing organizations to manufacture and supply our product candidates and certain raw materials used in the production thereof. Some of our key components for the production of Aspertec have a limited number of suppliers.

We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacture of our drug products. We will be relying on our contract manufacturers to successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others. In addition, although we will have no day-to-day control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, we are nonetheless responsible for ensuring that our drug products are manufactured in accordance with cGMPs. If the facilities that manufacture our drug products fail to maintain a cGMP compliance status acceptable to the FDA or a comparable foreign regulatory authority, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The FDA or a comparable foreign regulatory authority could also take enforcement action with regard to the facilities or the drug products.

We do not have commercial supply agreements with our suppliers. In the event that we and our suppliers cannot agree to the terms and conditions for them to provide clinical and commercial supply needs, we would not be able to manufacture our product candidates until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, our product candidates.

Our third-party suppliers may not be able to meet our supply needs or timelines and this may negatively affect our business. The failure of third-party manufacturers or suppliers to perform adequately or the termination of our arrangements with any of them may adversely affect our business.

***A key ingredient for our products is currently available from only a single provider.***

One key ingredient is currently limited to a single provider, Lipoid GmbH, or Lipoid, who supplies cGMP lecithin and is a leader in supplying high quality lipids to the global pharmaceutical industry. Lipoid developed this particular cGMP lecithin with us over a several year period, and has informed us that we are currently the only buyer of the product. We do not have a long-term contract with Lipoid for the supply of commercial quantities of this product, and there can be no assurances that Lipoid will be able to supply sufficient commercial quantities in compliance with regulatory requirements at an acceptable cost.

***We may be subject to costly product liability claims related to our products and product candidates and, if we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.***

We face the risk that the use of our product candidates may result in adverse side effects. Although we have product liability insurance, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer, and we may be required to increase our product liability insurance coverage as we increase the size of our operations. We do not know whether we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, on acceptable terms, if at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. To the extent that we are required to provide indemnities in favor of third parties, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates or products has caused an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- the inability to commercialize Aspertec or future product candidates;
- decreased demand for Aspertec or future candidates;
- regulatory investigations that could require costly recalls or product modifications;
- loss of revenue;
- substantial costs of litigation;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

***We currently have no sales and marketing staff or distribution organization. If we are unable to develop a sales and marketing and distribution capability on our own or through third parties, we will not be successful in commercializing our future products.***

We currently have no sales, marketing or distribution organization or history. To achieve commercial success for any approved product candidate, we must either develop a sales, marketing and distribution organization or outsource these functions to third parties. If we rely on third parties for marketing and distributing our approved products, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially within our control, and our product revenue may be lower than if we directly marketed or sold our products. We have no historical operations in this area, and if such efforts were necessary, we may not be able to successfully commercialize our future products. If we are not successful in commercializing our future products, either on our own or through third parties, any future product revenue will be materially and adversely affected.

***We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.***

The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies and biotechnology companies worldwide with respect to Aspertec and other product candidates that we may seek to develop or commercialize in the future. There are a number of pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates that compete directly or indirectly with Aspertec. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, safer or less costly than Aspertec or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in commercial sales, preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

Finally, the success of any product that is successfully commercialized will depend in large part on our ability to prevent competitors from launching a generic version that would compete with such product. If such competitors are able to establish that our patents are invalid or that the generic version would not infringe upon our product, they may be able to launch a generic product prior to the expected expiration of our relevant patents, and any generic competition could have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may fail to innovate and be competitive.***

We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire compounds or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, causing our revenues and operating results to suffer.

We expect to compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies. To successfully expand our product offerings, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with drugs.

***We may attempt to form collaborations in the future with respect to our products, but we may not be able to do so, which may cause us to alter our development and commercialization plans.***

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. For example, we have entered into a licensing arrangement with Lee's Pharmaceutical Holdings Limited for the commercialization of Aspertec in China and with an option for additional countries in Southeast Asia. We may attempt to find other strategic partners for other geographic jurisdictions and we may also attempt to find one or more strategic partners for the development or commercialization of one or more of our other product candidates. We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure appropriate terms is time-consuming and complex. We may not be successful in our efforts to establish such a strategic partnership for any product candidates and programs on terms that are acceptable to us, or at all.

Any delays in identifying suitable collaborators and entering into agreements to develop or commercialize our product candidates could negatively impact the development or commercialization of our product candidates in geographic regions where we do not have development and commercialization infrastructure. Absent a collaboration partner, we would need to undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected.

***We may be unable to realize the potential benefits of any collaboration.***

Even if we are successful in entering into a collaboration with respect to the development or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful. Collaborations may pose a number of risks, including:

- collaborators may not perform their obligations as expected;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time-consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in our achieving revenue to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

***We will need to grow our organization, and we may experience difficulties in managing growth.***

As of June 30, 2017, we had eleven full and part-time employees. We will need to expand our managerial, operational, financial and other resources in order to manage our operations, continue our development activities, commercialize Aspertec or other product candidates and comply with our obligations as a publicly reporting company. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our business strategy requires that we:

- manage our internal discovery and development efforts effectively while carrying out our contractual obligations to licensors, contractors, government agencies, any future collaborators and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- identify, recruit, maintain, motivate and integrate additional employees.

If we are unable to expand our managerial, operational, financial, and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

***We are highly dependent on the services of our executive management team, and on our ability to attract and retain qualified personnel.***

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. We are highly dependent on the principal members of our management and scientific staff, particularly our Executive Chairman of the Board, Michael J. Valentino, and our President and Chief Executive Officer, Natasha Giordano. If we are not able to retain Mr. Valentino, Ms. Giordano, or our incoming Chief Financial Officer, Rita O'Connor, or are not able to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. Although we have executed employment agreements with each member of our current executive management team, including Mr. Valentino, Ms. Giordano and Ms. O'Connor, we may not be able to retain their services as expected.

In addition, we have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

***Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.***

Our third-party manufacturers' activities and our own activities may involve the controlled storage, use and disposal of hazardous materials, including the components of our pharmaceutical product candidates, test samples and reagents, biological materials and other hazardous compounds. We and our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and/or interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations.

***We or the third parties upon whom we depend may be adversely affected by natural disasters.***

Changes to global climate, extreme weather and natural disasters could affect demand for our products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of our operations.

Our corporate headquarters is located in Houston, Texas, which in the past has experienced hurricanes. Hurricanes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our information technology systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

If such an event were to affect our supply chain, it could have a material adverse effect on our business.

***Our employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***If we are not able to implement the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 in a timely manner or with adequate compliance, we may be subject to sanctions by regulatory authorities.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and, beginning with our annual report for the year ending December 31, 2017, provide a management report on the internal control over financial reporting. If we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We will be evaluating our internal controls systems to allow management to report on, and eventually our independent auditors to attest to, the effectiveness of the operation of our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and eventual auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. The aforementioned auditor attestation requirements will not apply to us until we are no longer an “emerging growth company.”

To date, we have not conducted a review of our internal controls for the purpose of providing the reports required by these rules. We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or NASDAQ. Any such action could adversely affect our financial results or investors’ confidence in us and could cause our stock price to fall. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources and could materially adversely affect our stock price. Deficient internal controls could also cause us to fail to meet our reporting obligations or cause investors to lose confidence in our reported financial information, which could have a negative effect on our stock price.

***Our ability to utilize Dipexium’s or Old PLx’s net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the Merger.***

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Further, if the historic business of Dipexium is not treated as being continued by us for the two-year period beginning on the date of the merger (referred to as the “continuity of business requirement”), the pre-Merger net operating loss carryforward deductions become substantially reduced or unavailable for use by the surviving corporation in the transaction. It is expected that the Merger resulted in an “ownership change” of Dipexium. Accordingly, our ability to utilize Dipexium’s net operating loss and tax credit carryforwards will be substantially limited. These limitations, in turn, could result in increased future tax payments for the combined organization, which could have a material adverse effect on the business, financial condition or results of operations of the combined organization.

***We now possess not only all of the assets but also all of the liabilities of both Dipexium and Old PLx. Discovery of previously undisclosed or unknown liabilities could have an adverse effect on the combined organization's business, operating results and financial condition.***

Acquisitions involve risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. As a result of the Merger, we possess not only all of the assets, but also all of the liabilities of both Dipexium and Old PLx. Although Dipexium conducted a due diligence investigation of Old PLx and its known and potential liabilities and obligations, and Old PLx conducted a due diligence investigation of Dipexium and its known and potential liabilities and obligations, it is possible that undisclosed, contingent or other liabilities or problems may arise in the future, which could have an adverse effect on our business, operating results and financial condition.

#### **Risks Related to Product Safety and Efficacy Issues**

***Our understanding of the safety and efficacy of Aspertec could change as larger portions of the population begin using Aspertec.***

Aspertec, like all NSAIDs, poses specific risks, including stomach bleeding and, for aspirin, Reyes syndrome. As the product is used by additional patients, we may discover new risks associated with Aspertec which may result in changes to the distribution program and additional restrictions on the use of Aspertec which may decrease demand for the product. Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of standalone safety information and clinical trial data directly available to the public through websites and other means, e.g. periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action which may potentially cause our product sales or stock price to decline. Further, if serious safety, resistance or drug interaction issues arise with our marketed products, sales of these products could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected.

***Adverse safety events involving our marketed products may have a negative impact on our business.***

Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage physician and patient confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations. The reporting of adverse safety events involving our products or products similar to ours and public rumors about such events may increase claims against us and may also cause our product sales or stock price to decline or experience periods of volatility. Restrictions on use or significant safety warnings that may be required to be included in the label of our products — such as the risk of developing an allergic reaction to soy, stomach bleeding or Reyes syndrome, in the label for Aspertec — may significantly reduce expected revenues for this product and require significant expense and management time.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

***Our business will be highly dependent on professional and public reputation and perception, which may change, leading to volatile sales.***

Market perceptions of us are very important to our business, especially market perceptions of our company and brands and the safety and quality of our products. If we, our partners and suppliers, or our brands suffer from negative publicity, or if any of our products or similar products which other companies distribute are subject to market withdrawal or recall or are proven to be, or are claimed to be, ineffective or harmful to consumers, then this could have a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price. Also, because we are dependent on market perceptions, negative publicity associated with product quality, patient illness, or other adverse effects resulting from, or perceived to be resulting from, our products, or our partners' and suppliers' manufacturing facilities, could have a material adverse effect on our business, financial condition, results of operations, cash flows, or share price.

***We must be able to adapt to changed circumstances and quickly update product labels, which could be costly or harm our reputation.***

We may be required by regulatory authorities to change the labeling for any pharmaceutical product, including after a product has been marketed for several years. These changes are often the result of additional data from post-marketing studies, head-to-head trials, adverse events reports, studies that identify biomarkers (objective characteristics that can indicate a particular response to a product or therapy) or other studies or post-marketing experience that produce important additional information about a product. New information added to a product's label can affect its risk-benefit profile, leading to potential recalls, withdrawals, or declining revenue, as well as product liability claims. Sometimes additional information from these studies identifies a portion of the patient population that may be nonresponsive to a medicine or would be at higher risk of adverse reactions and labeling changes based on such studies may limit the patient population. The studies providing such additional information may be sponsored by us, but they could also be sponsored by competitors, insurance companies, government institutions, managed care organizations, scientists, investigators, or other interested parties. While additional safety and efficacy information from such studies can assist us and healthcare providers in identifying the best patient population for each product, it can also negatively impact our revenues due to inventory returns and a more limited patient population going forward. Additionally, certain study results, especially from head-to-head trials, could affect a product's reimbursement status or priority with certain payors, which could also adversely affect revenues.

## Risks Related to Intellectual Property

***If we are unable to obtain and maintain sufficient intellectual property protection for Aspertec or our future product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. However, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Further, the patentability of inventions, and the validity, enforceability and scope of patents in the pharmaceutical field involve complex legal and scientific questions and can be uncertain. As a result, patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries for many reasons. For example, since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Even if patents have issued, or do successfully issue, from patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market any of our product candidates under patent protection, if approved, would be reduced. Changes to the patent laws in the United States and other jurisdictions could also diminish the value of our patents and patent applications or narrow the scope of our patent protection.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.***

In addition to the protection afforded by patents, we rely on confidential proprietary information — including trade secrets and knowhow — to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements and invention assignment agreements with our employees and confidentiality agreements with consultants, scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

***We are parties to a lawsuit which, if adversely decided against us, could impact our rights to Locilex®.***

In April 2010, Dipexium acquired the worldwide rights to develop pexiganan, the active pharmaceutical ingredient in Locilex®, from Genaera Liquidating Trust, which was put in place to liquidate the assets of Genaera Corporation. In June 2012, Dipexium, along with its two senior executives and several other unrelated defendants, were sued in the Federal District Court for the Eastern District of Pennsylvania by a former shareholder of Genaera Corporation and purported to be on behalf of other Genaera Corporation shareholders, alleging, in pertinent part, that Dipexium's acquisition of the rights to pexiganan (the active ingredient in Locilex®, and which rights included the rights to the prior formulation of Locilex®) was for what was alleged to be inadequate consideration, and as a result, it was alleged that Dipexium and its senior executives aided and abetted a breach of fiduciary duty by Genaera Corporation and the Genaera Liquidating Trust to the former shareholders of Genaera Corporation. It was also alleged that Dipexium and its senior executives aided and abetted a breach of the duty of the trustee at common law and under a certain trust agreement which was alleged to exist and which was executed by Argyce LLC (or Argyce), as trustee. The agreement called for Argyce to create the Genaera Liquidating Trust pursuant to which Argyce apparently was appointed to liquidate the assets formerly held by Genaera Corporation. One of these assets was pexiganan, which Dipexium acquired via public auction conducted by Argyce on behalf of the Genaera Liquidating Trust.

The case against Dipexium and its senior executives was dismissed with prejudice by the Federal District Court, without leave to refile, on August 12, 2013 based on the argument that Plaintiff's claims were time barred, and a subsequent motion to reconsider such dismissal was denied by the Federal District Court. Prior to the dismissal there was no request or action to seek class certification by the plaintiff though it was purportedly filed on behalf of other former Genaera Corporation shareholders. Plaintiff appealed the dismissal of the suit as well as the denial of the motion to reconsider to the Third Circuit Appellate Court, which granted Plaintiff's appeal.

On October 17, 2014, the Third Circuit Appellate Court, in a 21 decision with a strong dissenting opinion, reversed the trial court's dismissal of Plaintiff's claims based on the expiration of the applicable statutes of limitation and remanded the case to the Federal District Court. In its opinion, the Third Circuit held that more information was necessary to determine when Plaintiff should have been on notice of his claims to determine the applicability of the discovery rule, which could serve to extend the time frame in which Plaintiff could bring his claims. Due to the strong dissent, all defendants filed the necessary documents requesting a petition for rehearing en banc, by the majority of the Third Circuit justices who are in active service. The Third Circuit denied the request for en banc hearing and remanded this case to District Court.

Upon remand to the Federal District Court, all defendants moved to dismiss the complaint for reasons other than being time barred. Dipexium and its executives moved for dismissal based on Plaintiff's inability to make a case for aiding and abetting a breach of fiduciary duty because there was no underlying breach and such an aiding and abetting claim requires an element of knowing participation in the fiduciary breach which cannot be established by Plaintiff.

The District Court held a hearing on this in September 2015 and the District Court delivered an Order on November 10, 2015 pursuant to which the District Court granted the Motion to Dismiss filed by each and every defendant including the Company and its executives. In December 2015, Plaintiff appealed the Federal District Court's decision to the Third Circuit Appellate Court and we anticipate a decision on whether to grant Plaintiff's appeal by the Third Circuit Appellate Court in 2017. We will continue to vigorously defend Plaintiff's claims on the factual record, which we believe will prove that we are not liable to the Plaintiff in any regard. If we were to lose this case, we could be required to pay damages, which could have a material adverse effect on us, our business plans and results of operations.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including post-grant or inter-partes proceedings, interference or derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. Even if we are successful in defending these claims, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be involved in lawsuits to protect or enforce our intellectual property rights which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, in whole or in part, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent.

Post-grant or inter-partes proceedings, interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as reexamination or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and/or management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could negatively affect our ability to compete in the marketplace.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong, or where standards are different than they are in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions, including China, where we currently have granted a license for Aspertec 325 mg. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.***

In addition to our own patents, an important patent family covering Aspertec is owned by the Board of Regents of The University of Texas System. Our development and commercialization of Aspertec is subject to our license agreement with The University of Texas System as is our license agreement with Lee's Pharmaceutical Holdings Limited. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations for achievement of certain milestones and royalties on product sales, as well as other material obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, The University of Texas System may have the right to terminate the applicable license in whole or in part. Specifically, Section 4.6 of our license agreement with The University of Texas System (as amended) provides that "Reasonable commercial diligence shall require that PLX . . . [o]n or before September 8, 2013, Sell or offer for Sale a Licensed Product." While we believe that we have exercised reasonable commercial diligence to actively attempt such commercialization, we have not yet successfully commercialized a licensed product. As such, the Board of Regents of The University of Texas System may have the option to terminate the license agreement, or to limit the exclusivity of the license in certain territories.

The loss of our license agreement with The University of Texas System could materially adversely affect our ability to proceed with the development or potential commercialization of Aspertec as currently planned, and could materially adversely affect our ability to proceed with any development or potential commercialization of PL1200 Ibuprofen and other NSAID programs. The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to consult and input into the patent prosecution and maintenance process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents.

***Limitations on intellectual property rights may result in other threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to Aspertec or our future product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- we may not develop or in-license additional proprietary technologies that are patentable.

*We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets of former or other employers.*

Some of our employees, consultants, advisors, and members of our Board of Directors, including our senior management, have been employed or retained by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or knowhow of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individuals' former or other employer. We are not aware of any material threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

#### **Risks Related to Government Regulation**

*The regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining, or cause delays in obtaining, approvals for the commercialization of Aspertec 81 mg or future product candidates, which will materially impair our ability to generate revenue.*

The design, development, research, testing, manufacturing, labeling, storage, recordkeeping, approval, selling, import, export, advertising, promotion, and distribution of drug products are subject to extensive and evolving regulation by federal, state and local governmental authorities in the United States, principally by the FDA, and foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. While we are permitted to market Aspertec 325 mg, neither we nor any future partner are permitted to market any other product candidate in the United States until we receive regulatory approval of a new drug application ("NDA") from the FDA.

We have not submitted an application or obtained marketing approval for doses of Aspertec other than the 325 mg dose, or for any other product candidate anywhere in the world. An NDA must include extensive preclinical and clinical data and supporting information to establish to the FDA's satisfaction the product candidate's safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product recalls;
- seizure of products;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

These actions could result in, among other things, substantial modifications to our business practices and operations; refunds of our products; the inability to obtain future approvals or marketing authorizations; and withdrawals or suspensions of current products from the market. Any of these events could disrupt our business and have a material adverse effect on our revenues, profitability and financial condition.

Prior to receiving approval to commercialize any future product candidates in the United States or abroad, we and any applicable collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Preclinical testing and clinical trials are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical trial could also cause the FDA or us to terminate a clinical trial or require that we repeat it or conduct additional clinical trials. Additionally, data obtained from preclinical studies and clinical trials can be interpreted in different ways and the FDA or other regulatory authorities may interpret the results of our studies and trials less favorably than we do. Even if we believe the preclinical or clinical data for a product candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of such product candidates and result in the FDA or other regulatory authorities denying approval of such product candidates for any or all targeted indications. The FDA or other regulatory authorities may determine that certain doses of Aspertec or any other product candidate that we develop are not effective, or are only moderately effective, or have undesirable or unintended side effects, toxicities, safety profile or other characteristics that preclude marketing approval or prevent or limit commercial use. In addition, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

***We are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.***

An approved product and its manufacturer are subject to continual review by the FDA and, as applicable, non-U.S. regulatory authorities. Any regulatory approval that we receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies or surveillance to monitor the safety and efficacy of the product. In addition, if the FDA or non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion, recordkeeping and submission of safety and other post-market information. Manufacturers of our products and manufacturers' facilities are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We, and our direct and indirect suppliers, remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. For example, the FDA conducts ongoing inspections to determine whether our record keeping, production processes and controls, personnel and quality control are in compliance with the cGMP regulations, and other FDA regulations. Adverse findings during regulatory inspections may result in the implementation of Risk Evaluation and Mitigation Strategies programs, completion of government mandated post-marketing clinical studies, and government enforcement action relating to labeling, advertising, marketing and promotion, as well as regulations governing manufacturing controls noted above. The FDA has increased its enforcement activities related to the advertising and promotion of pharmaceutical, biological and medical device products. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning advertising and promotion for our products. If we, any future collaboration partner or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the collaboration partner, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA also imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not restrict the promotion of our products only to their approved indications, we may be subject to enforcement action for off-label promotion. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- mandated modifications to promotional materials or the required provision of corrective information to healthcare practitioners;
- restrictions imposed on the product or its manufacturers or manufacturing processes;
- restrictions imposed on the labeling or marketing of the product;
- restrictions imposed on product distribution or use;
- requirements for post-marketing clinical trials;
- suspension of any ongoing clinical trials;
- suspension of or withdrawal of regulatory approval;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements;
- seizure or detention of our products;
- refusal to permit the import or export of our products;
- required entry into a consent decree, which can include imposition of various fines (including restitution or disgorgement of profits or revenue), reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- civil or criminal penalties; or
- injunctions.

Widely publicized events concerning the safety risk of certain drug products have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the imposition by the FDA of risk evaluation and mitigation strategies, or REMS, to ensure that the benefits of the drug outweigh its risks. In addition, because of the serious public health risks of high profile adverse safety events with certain products, the FDA may require, as a condition of approval, costly REMS programs.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, will not be permitted to market our future products and our business will suffer.

***Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.***

We may seek a distribution and marketing collaborator for Aspertec or other product candidates commercialized outside of the United States. In order to market our product candidates in the European Economic Area, or EEA (which comprises the 28 Member States of the EU, plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, we or our collaboration partners must obtain separate regulatory approvals. We have had limited interactions with foreign regulatory authorities, and approval procedures vary among countries and can involve additional clinical testing. In addition, the time required to obtain approval from foreign regulatory authorities may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on our ability to obtain approval in other countries. The foreign regulatory approval process generally includes all of the risks associated with obtaining FDA approval. In addition, in many

countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may or may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file, we may not receive necessary approvals to commercialize our product candidates in any market.

***Healthcare reform measures could hinder or prevent our product candidates' commercial success.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which is intended to contain or reduce the costs of medical products and services. The Affordable Care Act contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures that have impacted and will continue to impact existing government healthcare programs and will result in the development of new programs.

***We currently benefit from regulations that mandate full reimbursement without cost sharing for aspirin when prescribed by a health care provider. Changes to these regulations could significantly reduce reimbursement rates in a manner that negatively affects our sales.***

As a result of regulations enacted as part of the Affordable Care Act, we expect that Aspertec will qualify for 100% coverage when prescribed by physicians for the prevention of cardiovascular disease in patients with certain age-associated risks, requiring no out-of-pocket payments. While this will initially have the potential to expand the demand for Aspertec, changes to these regulations could have a significant adverse effect on reimbursement rates and, indirectly, on sales of Aspertec.

***We are subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.***

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"), which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Failure to comply with domestic and international privacy and security laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws, including protecting electronically stored information from cyberattacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

***Our international operations will be subject to the Foreign Corrupt Practices Act.***

As we pursue international licensing and sales arrangements outside the United States, we will be heavily regulated and expect to have significant interaction with foreign officials. Additionally, in many countries outside the United States, the health care providers who prescribe human pharmaceuticals are employed by the government and the purchasers of human pharmaceuticals are government entities; therefore, our interactions with these prescribers and purchasers would be subject to regulation under the Foreign Corrupt Practices Act, or FCPA, which prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business.

Compliance with these regulations may be costly, and may limit our ability to expand into certain markets. Further, we may inadvertently be found to be in violation of these and other regulations, which could result in material sanctions and penalties.

**Risks Related to Our Common Stock**

***The price of our common stock may be volatile.***

The market price for the shares of our common stock may fluctuate significantly in response to a number of factors including:

- ability to commercialize or delays in commercializing Aspertec;
- ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- any need to suspend or discontinue clinical trials due to side effects or other safety risks, or any need to conduct studies on the long-term effects associated with the use of our product candidates;
- manufacturing issues related to Aspertec, our product candidates for clinical trials or future products for commercialization;
- commercial success and market acceptance of our product candidates following regulatory approval;
- undesirable side effects caused by product candidates after they have entered the market;
- ability to discover, develop and commercialize additional product candidates;
- announcements relating to collaborations that we may enter into with respect to the development or commercialization of our product candidates, or the timing of payments we may make or receive under these arrangements;
- success of our competitors in discovering, developing or commercializing products;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims related to our clinical trials or product candidates;
- prevailing economic conditions;
- business disruptions caused by earthquakes or other natural disasters;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- healthcare reform measures in the United States;
- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- fluctuations in our quarterly operating results; and
- the issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of July 31, 2017, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 26.9% of our common stock. Accordingly, these stockholders have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these large stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. As an "emerging growth company," we can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

***Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.***

If our existing stockholders or holders of our options or warrants sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of June 30, 2017, we had outstanding a total of 8,686,010 shares of common stock.

***We may be at risk of securities class action litigation.***

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of each of our product candidates. In the past, pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and result in a decline in the market price of our common stock.

***Raising additional capital may cause dilution to our existing stockholders or involve the issuance of securities with rights, preferences and privileges senior to those of holders of our common stock.***

To raise capital, we may from time to time issue additional shares of common stock at a discount from the then-current trading price of our common stock. As a result, our common stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. Whether or not we issue additional shares of common stock at a discount, any issuance of common stock will, and any issuance of other equity securities or of options, warrants or other rights to purchase common stock may, result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to decline. New investors could also gain rights, preferences and privileges senior to those of holders of our common stock, which could cause the price of our common stock to decline.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove management.***

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of the outstanding combined company voting stock from merging or combining with the combined company. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

***Provisions of our charter documents limit the liability of our officers and directors, which could limit the ability of stockholders (and outside parties) to bring claims against such officers and directors.***

Our certificate of incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies, such as injunctive relief or rescission.

Our certificate of incorporation and our bylaws provide that we are required to indemnify our directors to the fullest extent permitted by Delaware law. Our bylaws also provide that, upon satisfaction of certain conditions, we shall advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our certificate of incorporation and bylaws provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

***We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; therefore capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.***

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

**None.**

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

**None.**

**ITEM 4. MINE SAFETY DISCLOSURE**

**Not Applicable.**

**ITEM 5. OTHER INFORMATION**

**Not Applicable.**

**ITEM 6. EXHIBITS**

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Form 10-Q.

**SIGNATURES**

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed by the undersigned hereunto duly authorized.

**PLX PHARMA INC..**

Date: August 11, 2017

/s/ Natasha Giordano  
President and Chief Executive Officer

/s/ Rita O'Connor  
Chief Financial Officer  
(Principal Accounting Officer)

## INDEX TO EXHIBITS

<b>Number</b>	<b>Description</b>
2.1	Agreement and Plan of Merger and Reorganization (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on December 22, 2016 (File No. 001-36351)).
3.1	Certificate of Amendment (Split Amendment) to the Certificate of Incorporation, as amended, of the Company, dated April 18, 2017 (incorporated by Reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
3.2	Certificate of Amendment (Name Change Amendment) to the Certificate of Incorporation, as amended, of the Company, dated April 19, 2017 (incorporated by Reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
3.3	Amended and Restated Certificate of Incorporation, as amended.*
4.1	Form of Warrant, to be issued by PLx Pharma Inc. to the Investors on June 14, 2017 (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed on June 12, 2017 (File No. 001-36351)).
10.1	Employment Agreement with Natasha Giordano, dated January 1, 2016 (incorporated by Reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
10.2	Amended and Restated Employment Agreement with David E. Jordan, dated April 1, 2016 (incorporated by Reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
10.3	Amended and Restated Employment Agreement with Gary Mossman, dated April 1, 2016 (incorporated by Reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
10.4	Amended and Restated Employment Agreement with Michael J. Valentino, dated April 1, 2016 (incorporated by Reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
10.5	Form of Indemnification Agreement (incorporated by Reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on April 20, 2017 (File No. 001-36351)).
10.6	PLx Pharma 2015 Omnibus Incentive Plan (incorporated by reference to Annex G to the Company's Registration Statement on Form S-4 filed on January 25, 2017 (File No. 333-215684)).
10.7	Executive Employment Agreement of Rita M. O'Connor, dated May 1, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on May 2, 2017 (File No. 001-36351)).
10.8	Separation and Settlement Agreement and Release of All Claims between PLx Pharma Inc. and David E. Jordan, dated May 1, 2017 (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on May 2, 2017 (File No. 001-36351)).
10.9	Amended and Restated Patent License Agreement, dated December 11, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on June 12, 2017 (File No. 001-36351)).

10.10	Amendment No. 1 to Amended and Restated Patent License Agreement, dated April 15, 2011 (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on June 12, 2017 (File No. 001-36351)).
10.11	Amendment No. 2 to Amended and Restated Patent License Agreement, dated December 17, 2011 (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on June 12, 2017 (File No. 001-36351)).
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Principal Executive Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of the Principal Financial and Accounting Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
99.1	Placement Agency Agreement, dated as of June 9, 2017, by and between PLx Pharma Inc. and Raymond James & Associates, Inc. (incorporated by reference to Exhibit 99.2 to the Company's Form 8-K filed on June 12, 2017 (File No. 001-36351)).
99.2	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 99.3 to the Company's Form 8-K filed on June 12, 2017 (File No. 001-36351)).
101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Label Linkbase Document.*
101.PRE	XBRL Taxonomy Presentation Linkbase Document.*

\* Filed herewith.

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION  
OF PLX PHARMA INC.**

*(reflecting Amendments filed April 18, 2017 and April 19, 2017)*

The undersigned, for the purposes of forming a corporation for conducting the business and promoting the purposes hereinafter stated, under the provisions and subject to the requirements of the laws of the State of Delaware (particularly Chapter 1, Title 8 of the Delaware Code and the acts amendatory thereof and supplemental hereto, and generally known as the “**Delaware General Corporation Law**”), does hereby make, file and record this Certificate of Incorporation, and does hereby certify as follows:

**FIRST:** The name of the corporation is PLx Pharma Inc. (hereinafter sometimes referred to as the “**Corporation**”).

**SECOND:** The address of the Corporation’s registered office in the State of Delaware is 1811 Silverside Road, Wilmington, DE 19810, New Castle County; and the name of the registered agent of the Corporation in the State of Delaware at such address is Vcorp Services LLC. The Corporation shall have the authority to designate other registered offices and registered agents both in the State of Delaware and in other jurisdictions.

**THIRD:** The nature of the business and the purposes to be conducted and promoted by the Corporation shall be to engage in any lawful business, to promote any lawful purpose, and to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law.

**FOURTH:** The capital stock of the Corporation shall be as follows:

1. Classes of Stock. The Corporation is authorized to issue one class of shares of capital stock to be designated as common stock (“**Common Stock**”). The number of shares of Common Stock authorized to be issued is one hundred million (100,000,000), par value \$0.001 per share.

2. Rights of the Common Stock. Except as otherwise provided by law or by the resolution or resolutions, the holders of outstanding shares of Common Stock shall have the exclusive right to vote for the election of directors and for all other purposes. Except as otherwise required by law or this Certificate of Incorporation of the Corporation, each holder of Common Stock is entitled to one vote for each share of Common Stock held of record by such holder with respect to all matters on which holders of Common Stock are entitled to vote. Subject to the Delaware General Corporation Law, dividends may be declared and paid on the Common Stock at such times and in such amounts as the Board of Directors of the Corporation (the “**Board of Directors**”) in its discretion shall determine. Upon the dissolution, liquidation or winding up of the Corporation, the holders of the Common Stock, as such, shall be entitled to receive the assets of the Corporation available for distribution to its stockholders ratably in proportion to the number of shares held by them.

3. Rights and Options. The Corporation has the authority to create and issue rights, warrants, options and other convertible securities entitling the holders thereof to purchase shares of any class or series of the Corporation’s capital stock or other securities of the Corporation, and such rights, warrants, options and other convertible securities shall be evidenced by instrument(s) approved by the Board of Directors. The Board of Directors is empowered to set the exercise price, duration, times for exercise and other terms and conditions of such rights, warrants, options or other convertible securities; provided, however, that the consideration to be received for any shares of capital stock subject thereto may not be less than the par value thereof.

4. Effective as of 4:30 P.M. eastern time, on April 19, 2017 (the “**Effective Time**”), the shares of Common Stock issued and outstanding immediately prior to the Effective Time and the shares of Common Stock issued and held in the treasury of the Corporation immediately prior to the Effective Time are reclassified into a smaller number of shares such that each eight (8) shares of issued Common Stock immediately prior to the Effective Time are reclassified into one (1) share of Common Stock. Notwithstanding the immediately preceding sentence, no fractional shares shall be issued and, in lieu thereof, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the reclassification shall be entitled to a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the Common Stock on The NASDAQ Capital Market on the last trading day prior to the Effective Time, or if such price is not available, the average of the last bid and asked prices of the Common Stock on such day or other price determined by the Corporation’s Board of Directors.

---

Each stock certificate that, immediately prior to the Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified (as well as the right to receive a whole share in lieu of a fractional share of Common Stock), provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified (including the right to receive a whole share in lieu of a fractional share of Common Stock).

**FIFTH:** The Corporation shall have perpetual existence.

**SIXTH:** For the management of the business, and for the conduct of the affairs, of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation and of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

1. The business of the Corporation shall be conducted by the officers of the Corporation under the supervision of the Board of Directors.
2. The number of directors which shall constitute the whole Board of Directors shall be fixed by, or in the manner provided in, the Bylaws of the Corporation (the "**Bylaws**"). No election of Directors need be by written ballot.
3. Notwithstanding any other provision of law, all action required to be taken by the stockholders of the Corporation shall be taken at a meeting duly called and held in accordance with the law, this Certificate of Incorporation and the Bylaws, or by written consent signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

**SEVENTH:**

1. The Corporation may, to the fullest extent permitted by Section 145 of the Delaware General Corporation Law, as the same may be amended and supplemented, indemnify any and all persons whom it shall have power to indemnify under said section from and against any and all of the expenses, liabilities, costs, fees or other matters referred to in or covered by said section, and the indemnification provided for herein shall not be deemed exclusive of any other rights to which a person indemnified may be entitled under any Bylaw, agreement, insurance, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

2. No director shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty by such director as a director. Notwithstanding the foregoing sentence, a director shall be liable to the extent provided by applicable law: (i) for breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the Delaware General Corporation Law or (iv) for any transaction from which the director derived an improper personal benefit. No amendment to or repeal of this paragraph (2) of this Article Seventh shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such Director occurring prior to such amendment.

---

**EIGHTH:** From time to time any of the provisions of this Certificate of Incorporation may be amended, altered or repealed, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted in the manner and at the time prescribed by said laws, and all rights at any time conferred upon the stockholders of the Corporation by this Certificate of Incorporation are granted subject to the provisions of this Article EIGHTH.

**NINTH:** Whenever a compromise or arrangement is proposed between this Corporation and its creditors or any class of them and/or between this Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of this Corporation or of any creditor or stockholder thereof or on the application of any receiver or receivers appointed for this Corporation under the provisions of Section 291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for this Corporation under the provisions of Section 279 of Title 8 of the Delaware Code order a meeting of the creditors or class of creditors, and/or of the stockholders or class of stockholders of this Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three-fourths in value of the creditors or class of creditors, and/or of the stockholders or class of stockholders of this Corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of this Corporation as a consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, and/or on all the stockholders or class of stockholders, of this Corporation, as the case may be, and also on this Corporation.

**TENTH:** In furtherance and not in limitation of the power conferred by statute, the Board of Directors is expressly authorized to make, alter, amend or repeal the Bylaws of the Company.

**SECTION 302**  
**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**

I, Natasha Giordano, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of PLx Pharma Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its unconsolidated investments, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2017

By: /s/ Natasha Giordano  
Natasha Giordano, President and Chief Executive Officer

**SECTION 302**  
**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER**

I, Rita O'Connor, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of PLx Pharma Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its unconsolidated investments, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2017

By: /s/ Rita O'Connor  
Rita O'Connor, Chief Financial Officer (Principal Financial Officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO  
18 U.S.C. SECTION 1350 AND EXCHANGE ACT RULES 13a-14(b) AND 15d-14(b)  
(Section 906 of the Sarbanes-Oxley Act of 2002)**

In connection with the Quarterly Report of PLx Pharma Inc. (the "Company") on Form 10-Q for the period ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Natasha Giordano, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of the operation of the Company.

*/s/ Natasha Giordano*

\_\_\_\_\_  
Natasha Giordano, President and Chief Executive Officer

August 11, 2017

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO  
18 U.S.C. SECTION 1350 AND EXCHANGE ACT RULES 13a-14(b) AND 15d-14(b)  
(Section 906 of the Sarbanes-Oxley Act of 2002)**

In connection with the Quarterly Report of PLx Pharma Inc. (the "Company") on Form 10-Q for the period ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Rita O'Connor, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge and belief:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of the operation of the Company.

*/s/ Rita O'Connor*

\_\_\_\_\_  
Chief Financial Officer (Principal Financial Officer)

August 11, 2017

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

