Table of Contents

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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2017
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____to _____

Commission file number 001-36351

PLX PHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-4995704**
(State of incorporation)	(I.R.S. employer identification no.)
8285 El Rio Street, Ste. 130 **Houston, Texas**	**77054**
(Address of principal executive offices)	(Zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: Not applicable

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 ☐ 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 Exchange Act Rule 12b-2). Yes ☐ No ☒

As of June 30, 2017 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the common stock of the registrant (based upon the closing price of the registrant's common stock at that date as reported by the NASDAQ Capital Market), excluding outstanding shares beneficially owned by directors and executive officers, was approximately $42.9 million.

As of March 1, 2018, there were 8,725,060 shares outstanding of the registrant's common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to the 2018 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

PART I

ITEM 1.	BUSINESS	6
ITEM 1A.	RISK FACTORS	21
ITEM 2.	PROPERTIES	46
ITEM 3.	LEGAL PROCEEDINGS	46
ITEM 4.	MINE SAFETY DISCLOSURES	47

PART II

ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	48
ITEM 6.	SELECTED FINANCIAL DATA	49
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	49
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	54
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	54
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	54
ITEM 9A.	CONTROLS AND PROCEDURES	54
ITEM 9B.	OTHER INFORMATION	56

PART III

ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	56
ITEM 11.	EXECUTIVE COMPENSATION	56
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	56
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	56
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	56

PART IV

ITEM 15.	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	56

PART I

Unless the context otherwise requires, references in this Annual Report on Form 10-K (this "Form 10-K") to the "Company," "we," "us," and "our" refer to PLx Pharma Inc. and its consolidated subsidiaries.

Information Regarding Forward-Looking Statements

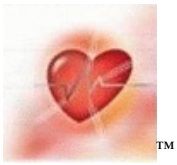
This Form 10-K and certain information incorporated herein by reference may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and involve assessments of certain risks, developments, and uncertainties in our business looking to the future, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative versions of these words and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based 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 that we believe to be reasonable as of the date of this Form 10-K. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors" of this Form 10-K, which could cause our future operating results to differ materially from those set forth in any forward-looking statement. In light of these risks, uncertainties and assumptions, there can be no assurance that any such forward-looking events or circumstances included herein can be realized, 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 such forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments. Forward-looking statements include, but are not limited to, statements about:

- our ability to bring our lead product candidates, 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;
- 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, including but not limited to any milestone payments or royalties;
- legal, political judicial and regulatory changes;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

Note Regarding Trademarks

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

- PLX®
- PLXPHARMA®
- PLXGUARD™
- ASPERTEC™
-  ™

Solely for convenience, the trademarks and trade names in this Form 10-K are sometimes referred to without the TM 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. □

ITEM 1. BUSINESS.

Overview

We are a late-stage specialty pharmaceutical company initially focused on developing our clinically validated and patent-protected PLxGuard delivery system to provide more effective and safer 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 ("FDA") approved lead product, Aspertec 325 mg, is a novel formulation of aspirin using the PLxGuard delivery system that is intended to provide better antiplatelet effectiveness for cardiovascular disease prevention and significantly reduce acute GI side effects 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 ("sNDA"), leveraging the already approved status of Aspertec 325 mg.

Products and Strategy

Our commercialization strategy will target both the over-the-counter ("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 next generation aspirin product. Our product pipeline also includes other oral 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 ("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-filled 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 than 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 to 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 ("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 Form 10-K 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. We will rely on the clinical results of Aspertec 325 mg for the Aspertec 81 mg sNDA and do not anticipate any additional clinical trials will be required, effectively positioning this product as an end of Phase 3 status. Our goal is to begin selling both products in the United States by mid-2020, subject to approval by the FDA.

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 ("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 approval process and may qualify for the 505(b)(2) NDA path.

Manufacturing and Supplies

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop or own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required ingredients and finished products for Aspertec and other product candidates. We do not have any long-term contracts with any of these third parties. We do not have any contractual relationships for the manufacture of commercial supplies of Aspertec or other product candidates if they are approved. We have entered into a Master Services Agreement with a U.S. based contract manufacturer and packager for commercial supplies of Aspertec. As our commercial sales grow we anticipate entering into agreements with one or more back-up manufacturers as appropriate for additional commercial production of Aspertec or other product candidates. We currently employ internal resources to manage our manufacturing contractors. The relevant manufacturers and potential manufacturers of Aspertec have orally advised us that they are compliant with both current Good Manufacturing Practices ("cGMP") and current Good Laboratory Practices ("cGLP"). There can be no assurance that Aspertec or other product candidates, if approved, can be manufactured in sufficient commercial quantities, in compliance with regulatory requirements and at an acceptable cost.

We and our contract manufacturers are and will be subject to extensive government regulation in connection with the manufacture of any pharmaceutical product. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP and cGLP for drugs on an ongoing basis, as mandated by the FDA and other regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

We believe that most of the ingredients we require to manufacture Aspertec are readily available from multiple supp liers and are commonly used in the pharmaceutical industry. One key ingredient is currently limited to a single provider, Lipoid GmbH ("Lipoid"), which supplies cGMP lecithin and is a leader in supplying high quality lipids to the global pharmaceutical industry. Lipoid is subject to a confidentiality agreement and developed this cGMP lecithin with us over a several year period and currently we are the only buyer of this product. Lipoid has represented the capability to provide this product from two different manufacturing sites in Germany, mitigating the risk of a shutdown at one site ceasing supply. We do not at this time have any 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.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis of proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates include the therapeutic efficacy, safety and tolerability profiles and cost. Many of our competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Consequently, our competitors may develop products that may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

Aspertec faces competition from many companies with OTC aspirin products. These include branded products from Bayer AG, Prestige Brands, Inc. (Ecotrin, Goody's, BC Powder) and Foundation Consumer Healthcare, LLC (St. Joseph) and private label or store brands (CVS, Walgreens). Aspirin is approved in the United States for multiple uses. In addition to cardiovascular disease prevention and treatment, OTC aspirin may be used for the treatment of pain, inflammation and fever. There are two aspirin products for cardiovascular disease prevention that are approved by the FDA for prescription use owned by Aralez Pharmaceuticals Inc. (Yosprala) and Espero BioPharma, Inc. (Durlaza). There are a variety of aspirin and NSAID products in various stages of development in the United States and globally that represent potential competition when and if they become approved by the FDA and are commercialized. Companies and academic institutions involved include Takeda Pharmaceutical Company Limited (Takeda), Oxford Pharmascience Group Plc, Antibe Therapeutics Inc. and The City College of New York. PL2200 Aspirin and other pain and inflammation product candidates such as PL1200 Ibuprofen will face competition from many firms. These include OTC and prescription products. Major competitors include Pfizer Inc. (Advil), Johnson & Johnson (MotrinIB, Tylenol), Bayer AG (Aleve) and private label or store brands (CVS, Walgreens).

The aspirin market is currently predominantly composed of generic products either branded (e.g. Bayer) or private label (e.g. CVS). Aspertec 325 mg is the only liquid-filled aspirin capsule product to be approved by the FDA. Aspertec 325 mg went through a different regulatory approval process than the current OTC aspirin products being marketed in the US. Aspertec 325 mg was approved under the 505(b)(2) NDA process and, when launched, is expected to be the only OTC available aspirin based product that successfully passed this rigorous process. We believe the clinical trials that demonstrated better efficacy and safety will assist us in differentiating Aspertec from the competition. Other product candidates will undergo clinical trials to provide differentiation as part of their product development and commercialization.

Intellectual Property

Our success depends, in part, upon our ability to protect our core novel technology. To establish and protect our proprietary rights we rely on a combination of patents, patent applications, trademarks, copyrights, trade secrets and know-how, license agreements, confidentiality procedures, non-disclosure agreements with third parties, employee disclosure and invention assignment agreements, and other contractual rights.

Patent Portfolio

On January 8, 2003, we entered into a worldwide, exclusive license agreement with The Board of Regents of the University of Texas System ("UT"), as described in more detail in the section herein titled "License Agreements—UT License Agreement", which was amended, restated on December 11, 2009, and subsequently amended on April 15, 2011 and on December 17, 2011 (as amended, the "UT License Agreement"). The patents in-licensed under the UT License Agreement constitute an important part of our intellectual property. This family of patents includes composition of matter, methods of manufacturing and methods of treatment that provide protection for PL2200 Aspirin, PL1200 Ibuprofen and other NSAID product candidates in the United States and in a number of global markets. The following is a summary of the patents in-licensed under the UT License Agreement and their respective expiration dates:

- *Methods and compositions employing formulations of lecithin oils and NSAIDs for protecting the gastrointestinal tract* – includes five issued U.S. patents with the earliest expiration on December 19, 2021 and the latest expiring on March 23, 2022, and 24 issued patents in other jurisdictions expiring on December 19, 2021, and two pending patent applications in Brazil and Hong Kong.

- *Compositions and methods for treating and/or ameliorating cancer, the onset of cancers or the symptoms of cancers* – includes one issued U.S. patent expiring on May 22, 2026, and five issued patents in other jurisdictions, including Australia, Canada, China, Hong Kong and Singapore, expiring on August 2, 2024.

- *Sterile preparations of phospholipids and anti-inflammatory pharmaceuticals and methods of making and using same* – includes five issued patents in foreign jurisdictions, including Australia, Canada, India, Israel and Singapore, expiring on August 2, 2024.

- *Purified phospholipid non-steroidal anti-inflammatory drug associated compositions and methods of preparing and using same* – includes one issued U.S. patent expiring on June 3, 2026 and two issued patents in other jurisdictions, including Australia and Mexico, expiring on October 12, 2025.

We have developed our own patent applications, some of which have issued and others, if issued with claims as filed, will provide patent protection for Aspertec 325 mg and 81 mg, other NSAID products and will broaden the opportunity for new products to include many different drug classes. The "*pH dependent carriers for targeted release of pharmaceuticals along the gastrointestinal tract, compositions therefrom and making and using same"* family of patent applications are issued in the U.S., China and Mexico and we have pending applications in Europe, Australia, Canada, Hong Kong, India, Japan, Mexico and South Korea which, if issued with claims as filed, are expected to provide patent protection through September 29, 2032. In the United States we have issued three patents from the "*pH dependent carriers for targeted release of pharmaceuticals along the gastrointestinal tract, compositions therefrom and making and using same*" family consisting of U.S. patent numbers 9216150, 9226892 and 9730884, expiring on September 29, 2032, in China number ZL201280058596X expiring on September 28, 2032, and in Mexico we have issued patent number 340951 expiring on September 29, 2032.

U.S. patent numbers 8,865187 and 9351984 with "*Compositions comprising lecithin oils and NSAIDs for protecting the gastrointestinal tract and providing enhanced therapeutic activity*", U.S. patent number 9,101637 with "*Methods of treating inflammation with compositions comprising lecithin oils and NSAIDs for protecting the gastrointestinal tract and providing enhanced therapeutic activity,*" and U.S. patent numbers 9216150 and 9226892 with "*pH dependent carriers for targeted release of pharmaceuticals along the gastrointestinal tract, compositions therefrom and making and using same*" are listed in the FDA Orange Book. As new patents are issued relative to FDA approved products such as Aspertec 325 mg and 81 mg , they will be added to the Orange Book and, as new products are approved by the FDA, the relevant patents will be added to the Orange Book. The Orange Book lists patents that protect each drug. Patent listings and use codes are provided by the drug application owner, and the FDA is obliged to list them. In order for a generic drug manufacturer to win approval of a drug under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), the generic manufacturer must certify that they will not launch their generic pharmaceutical product until after the expiration of the Orange Book-listed patent, or that the patent is invalid, unenforceable, or that the generic product will not infringe the listed patent.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review.

License Agreements

UT License Agreement

On January 8, 2003, we entered into the UT License Agreement with UT. The patents in-licensed under this agreement constitute an important part of our intellectual property. This family of patents includes composition of matter, methods of manufacturing and methods of treatment that provide protection for PL2200 Aspirin, PL1200 Ibuprofen and other NSAID product candidates in the United States and in a number of global markets. Pursuant to the UT License Agreement, UT granted us an exclusive license under its patents and know-how related to their NSAID-phospholipid technology to develop and commercialize NSAID products for use anywhere in the world. Certain of the technology was developed with government funding, and the exclusivity of our license is therefore subject to certain retained rights of the U.S. federal government. We are responsible for the development and commercialization of the licensed products under the agreement. The agreement is in effect as long as the patents are valid and we may terminate this agreement at our option with appropriate notice. Also, if we fail to actively attempt to commercialize licensed products for a specific period of time, UT may have the option to terminate or limit the exclusivity of the license in certain territories. Specifically, Section 4.6 of the UT License Agreement provides that "Reasonable commercial diligence shall require that the Company . . . . [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, UT may have the option to terminate the license agreement, or to limit the exclusivity of the license in certain territories. The agreement provides for milestone payments related to the first product to obtain regulatory approval to sell a licensed product, which milestone payments have been paid. The agreement provides for future potential milestone payments based upon the aggregate revenue from the sale of all licensed products in aggregate totaling $350,000. It is unlikely that any of these milestones will be triggered in the next twelve months. In addition to the milestone payments, we will owe a royalty on the net sales of the licensed products. The amount of the royalty depends upon who is selling the product. Should we commercialize a product ourselves there is a running royalty obligation in the low single digit range based upon net sales. If a product is commercialized by another company under a sublicense agreement with us, then UT receives a share of consideration received by us that is in the low double-digit range. There is a minimum annual royalty payment obligation. We are responsible for the prosecution and maintenance of the licensed patents at our expense and for the prosecution and control of any action for infringement related to any product that does, or may, compete with one of our marketed licensed products and any claim within a licensed patent that covers or relates to such marketed licensed product.

International License Agreement with Lee's

On March 12, 2012, the Company entered into a license agreement with Lee's Pharmaceutical Holdings Limited, Zhaoke Pharmaceutical (HEFEI) Co. Ltd and Lee's Pharmaceutical (Guangzhou) Limited (collectively, "Lee's") granting Lee's exclusive rights to develop PL2200 Aspirin in the People's Republic of China, including Hong Kong and Macao special Administrative Regions (the "Lee's Agreement"). This agreement was amended on December 31, 2013, amended and restated effective June 19, 2015, and subsequently terminated by mutual agreement of the parties thereto on October 31, 2017. This agreement was a sublicense of UT patents in-licensed pursuant to the UT License Agreement providing Lee's access to these and the Company's patents. As of October 31, 2017, the Company has received $400,000 in payments per the terms of the Lee's Agreement.

Government Regulation

Government authorities in the United States, at the federal, state and local level, in the European Union, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug Approval Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (the "FDCA"), implementing regulations and other federal and state statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's cGLP regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices ("cGCP") to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical studies and submission of an IND

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess a product's potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless during such 30-day period the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent (assent, if applicable) in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the clinical trial patients are being exposed to an unacceptable health risk. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee, which is typically increased annually. Under the new Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of ten months from the date of the FDA's acceptance for filing of a standard non-priority NDA to review and act on the submission.

As a condition of NDA approval, the FDA also may require submission of a risk evaluation and mitigation strategy ("REMS") plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA may refer an application for a novel drug to an advisory committee, which is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured, which is not under the control of the product sponsor. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If, or when, those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-approval requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies to determine compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend significant time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although doctors may prescribe drugs for off-label purposes. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. In addition, prescription drug manufacturers in the United States must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

Section 505(b)(2) NDAs

Most drug products obtain FDA marketing approval pursuant to an NDA or an abbreviated new drug application ("ANDA"). A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on FDA's prior findings of safety and/or effectiveness for a similar product or published literature in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety and/or effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Hatch-Waxman exclusivity

Marketing exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity ("NCE") if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the NCE exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement (a Paragraph IV certification). If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

NDA vs. OTC Monograph products

OTC drugs can be brought to market via two routes: the NDA approval process and the OTC monograph process. A drug product is eligib le to be brought to market via the OTC monograph process if it is not a new drug, and the drug product meets the FDA's established conditions for general recognition of safety and effectiveness ("GRASE"). The OTC drug monographs are a kind of "rule book" of conditions for each therapeutic category covering acceptable ingredients, uses (indications), doses, formulations, labeling, and testing.

The OTC Drug Review is a three-phase public rulemaking process established by the FDA to evaluate the safety and effectiveness of OTC drug products marketed in the United States prior to May 11, 1972. The three-phase rulemaking process can be summarized as follows:

1) Advisory Review Panel — Advisory review panel appointed by the FDA analyzes data available on OTC drug active ingredients to determine if the active ingredients can be classified as GRASE, not GRASE, or insufficient data are available. Results of the advisory review panel's analyses are published in the Federal Register as an Advance Notice for Proposed Rulemaking ("ANPR").

2) Tentative Final Monograph — After the FDA reviews the advisory review panel's findings, as well as additional data that may have become available and the public's comments, the FDA publishes its conclusions in the Federal Register as a Proposed Rule also called a Tentative Final Monograph ("TFM").

3) Final Monograph — After publication of the TFM, a period of time is allotted for interested parties to submit comments or data in response to the FDA's proposal. The final regulations in the form of drug monographs provide a standard for GRASE OTC drug products.

If a product deviates from the conditions under the TFM or final monograph and was not marketed before May 1972, then the drug product is considered a new drug and requires an NDA to be legally marketed. Aspirin was classified into the therapeutic class for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products ("IAAA"). The ANPR was published in 1977, and in 1988, the FDA published the TFM for IAAA. The IAAA TFM recommends appropriate labeling, including therapeutic indications, dosage instructions, and warnings about side effects and ways of preventing misuse. Although it has been updated and amended since its original publication, the IAAA monograph has not been finalized.

Differences between the NDA approval process and the OTC monograph process are listed below.

NDA Approval Process	**OTC Monograph Process**
Pre-market approval — FDA review and approves formulation and labeling prior to marketing.	No pre-market approval — FDA sets forth specific conditions for GRASE, or in the case of a developing monograph, sets forth conditions that allow for continued marketing pending a final monograph.
Confidential filing	Public process
Drug-product specific	Active ingredient-specific and evaluated by OTC drug category
May require a user fee	No user fees
Potential for marketing exclusivity	No marketing exclusivity

FDA review timelines	Manufacturers responsible for ensuring compliant product with no FDA-mandated review (either pre- or post-market)
May require clinical studies, including studies on label comprehension and actual use	Generally does not require clinical studies. Label comprehension and actual use studies are not required for ingredients already covered by a final or tentative final monograph.
Approved labeling is unique to the drug	Labeling is defined by the monograph. Once marketed, FDA can review the complete labeling at any time to determine whether it is truthful or misleading.
Approved NDA is "license" to market	Final monograph is open to anyone
Trade name reviewed prior to marketing	No review of trade name prior to marketing. Once marketed, FDA can review the trade name at any time.

When Aspertec 325 mg is commercialized, we believe it will be the only NDA-approved OTC aspirin product available. Approval of the PL2200 NDA granted PL2200 labeling similar to that of monograph aspirin products.

Professional Labeling

Although the IAAA TFM has not been finalized for OTC use, final regulations for the professional labeling of aspirin were published in 1988. Professional labeling is labeling that provides specific information to health professionals for uses not included in OTC drug labeling. Professional labeling can be provided solely to healthcare professionals. Professional labeling may not be used on consumer products or on consumer-directed labeling. Under the IAAA regulations for professional labeling of aspirin, patients can only use aspirin for cardiovascular-related uses when directed to do so by a physician.

Professional labeling for aspirin includes the following indications:

- Vascular Indications (Ischemic Stroke, Transient Ischemic Attack (TIA), Acute Myocardial Infarction ("MI"), Prevention of Recurrent MI, Unstable Angina Pectoris, and Chronic Stable Angina Pectoris): Aspirin is indicated to: (1) reduce the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, (2) reduce the risk of vascular mortality in patients with a suspected acute MI, (3) reduce the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, and (4) reduce the combined risk of MI and sudden death in patients with chronic stable angina pectoris.

- Revascularization Procedures (Coronary Artery Bypass Graft ("CABG"), Percutaneous Transluminal Coronary Angioplasty ("PTCA"), and Carotid Endarterectomy): Aspirin is indicated in patients who have undergone revascularization procedures (i.e., CABG, PTCA, or carotid endarterectomy) when there is a preexisting condition for which aspirin is already indicated.

- Rheumatologic Disease Indications (Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Spondyloarthropathies, Osteoarthritis, and the Arthritis and Pleurisy of Systemic Lupus Erythematosus ("SLE")): Aspirin is indicated for the relief of the signs and symptoms of rheumatoid arthritis, juvenile rheumatoid arthritis, osteoarthritis, spondyloarthropathies, and arthritis and pleurisy associated with SLE.

FDA Oversight vs. FTC Oversight

Since 1971, the FDA and the Federal Trade Commission (the "FTC") have had a Memorandum of Understanding in place, which dictates that the FDA has primary responsibility over OTC drug labeling, while the FTC has primary responsibility over OTC drug advertising.

	Rx Products	OTC Products
Labeling	FDA	FDA
Advertising	FDA	FTC

For an NDA-approved product, OTC labeling, including the labeling on the box, must be submitted to the FDA for review and approval prior to distribution. As indicated above, this is different from monograph products, which are not subjected to the FDA's labeling review and approval processes prior to launching to market. Advertising for OTC products is under the purview of the FTC. Promotional material (including print, radio, and/or TV) is not required to be submitted to the FTC prior to distribution, unlike Rx promotional materials submitted to the FDA.

Under FTC regulations, claims in advertisements, including OTC medicine advertisements, must be truthful and cannot be misleading or unfair.

Advertisers must have substantiation that all objective express and implied claims in advertising are true before making the claims. The standard for substantiation of health claims is "competent and reliable scientific evidence." For drug claims, competent and reliable scientific evidence generally has been interpreted as requiring at least one or two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.

Beyond FTC regulation of advertising, industry self-regulation plays an important role. The National Advertising Division ("NAD") of the Council of Better Business Bureaus reviews advertising complaints by competitors. NAD generally applies the same standard as the FTC. If NAD determines that the substantiation does not support the claims or that it is otherwise false and misleading, it will recommend that the advertiser revise or discontinue the advertisement. If the advertiser does not agree to do so, NAD will forward the case to the FTC or the FDA for review.

Foreign Regulatory Approval Process

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, we must obtain approval from both the competent national authority of a European Union member state in which the clinical trial is to be conducted, and a favorable opinion from the competent ethics committee. Our clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, we may submit a Marketing Authorization Application ("MAA") either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP") established at the European Medicines Agency (the "EMA") is responsible for conducting the initial assessment of a drug. The CHMP also is responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is requested by the CHMP but has not yet been provided. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not previously received marketing approval in any European Union member state. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

In the European Union, new chemical entities qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the drug if such company can complete a full MAA with a complete database of pharmaceutical test, preclinical tests and clinical trials and obtain marketing approval of its product.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services and questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as our drug product candidates and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, which we collectively refer to as the Affordable Care Act ("ACA"), contains provisions that have the potential to substantially change healthcare financing, including impacting the profitability of drugs. For example, the ACA revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations and subjected manufacturers to new annual fees and taxes for certain branded prescription drugs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescribing of any product candidates for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products that obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal false claims laws and civil monetary penalties law impose penalties and provide for civil whistleblower or qui tam actions against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without written authorization;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the ACA require manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and certain physician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to our business operations, including our sales or marketing arrangements, and claims involving healthcare items or services reimbursed by governmental third-party payors, and in some instances, also such claims reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (the "FCPA") 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. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the Company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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 FCPA.

In addition to the U.S. application and enforcement of the FCPA, the various jurisdictions in which we operate and supply our products have laws and regulations aimed at preventing and penalizing corrupt and anticompetitive behavior. In recent years, several jurisdictions, including China, Brazil, and the United Kingdom, have enhanced their laws and regulations in this area, increased their enforcement activities, and/or increased the level of cross-border coordination and information sharing.

Employees

As of December 31, 2017, we had 14 employees, of which 11 are full time employees. Of these full-time employees, four work on research and development, manufacturing, and clinical operations and seven work in sales, marketing, management and administration. We also use the services of numerous outside consultants in business and scientific matters. None of our employees are represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Compliance with Environmental Regulations

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.

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. We have not incorporated by reference into this Form 10-K the information in, or that can be accessed through, our website and you should not consider it to be a part of this Form 10-K.

On April 19, 2017, Dipexium Acquisition Corp., a Delaware corporation ("Merger Sub") and a wholly-owned subsidiary of Dipexium Pharmaceuticals, Inc., a Delaware corporation ("Dipexium"), merged with and into PLx Pharma Inc., a privately-held Delaware corporation ("Old PLx"), pursuant to the terms of that certain Agreement and Plan of Merger and Reorganization dated as of December 22, 2016 by and among Dipexium, Merger Sub and Old PLx (the "Merger"). As part of the Merger, Dipexium was re-named PLx Pharma Inc. and Old PLx was re-named PLx Opco Inc. Following completion of the Merger, Old PLx became a wholly-owned subsidiary of the Company. Since the completion of the Merger, the business we have conducted has been primarily the business of Old PLx.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. We have described below a number of risk factors which, in addition to uncertainties, risks and other information presented elsewhere in this Form 10-K, including our consolidated financial statements and notes thereto, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below, as well as those presented elsewhere in this Form 10-K, should be considered carefully in evaluating the Company, our business and the value of our securities. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. Please also read carefully the section entitled "Information Regarding Forward-Looking Statements" included in this Form 10-K.

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 and grant activities, and have incurred losses in each year since we commenced operations. The Company's net loss for the year ended December 31, 2017 was $15.3 million. As of December 31, 2017, we had an accumulated deficit of approximately $67.3 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, regulatory and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future; and
- acquire or in-license other product candidates and technologies.

Even if we do generate revenues, we may never achieve profitability. 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 December 31, 2017, we had working capital of approximately $23.9 million and cash and cash equivalents of approximately $24.4 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. On August 9, 2017, the Company entered into 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.

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:

- the timing of, and costs involved in, seeking and obtaining FDA and other regulatory approvals;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- the emergence of competing technologies and other adverse market developments;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- our revenue, if any, from successful commercialization of our product candidates;
- the costs associated with being a public company.
- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- 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;
- our ability to enter into additional collaboration, licensing or other arrangements, including collaborative agreements to support the development of our product candidates, and the terms and timing of such arrangements; and
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future.

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 the medical community, patients 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 IRB, 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.

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 Aspertec and any potential 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 candidate, including cost and clinical benefit relative to alternative treatments;
- the 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 the product candidate;
- 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 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 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.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of Aspertec or our other product candidates and conduct required stability testing, issues may arise involving quality, ingredient inconsistencies, product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to proceed with commercial marketing of Aspertec or our other product candidates. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our product or delivery devices could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, or failure to obtain or maintain approval for our products.

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 a comparable foreign regulatory authority. 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 currently 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.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification, or FDA approval. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay approval of our product candidates; and jeopardize our ability to commence product sales and generate revenue.

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 (“Lipoid”), which 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 and as a result may expose us to significant product liability claims. Although we currently have product liability insurance coverage in the amount of $5 million, 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, marketing and distribution organization or history. If we are unable to establish effective sales, marketing and distribution capabilities or enter into third party arrangements for sales, marketing and distribution, we may not be able to effectively market, sell and distribute our product candidates, if approved.

We are currently in the process of building our sales and marketing staff and distribution processes. 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. 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 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. We may attempt to find strategic partners for the commercialization of Aspertec in 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 December 31, 2017, we had 14 employees, of which 11 are full 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 public 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, our President and Chief Executive Officer, Natasha Giordano, and our Chief Financial Officer, Rita O'Connor. If we are not able to retain Mr. Valentino, Ms. Giordano or Ms. 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 various environmental, health and safety laws and regulations, including 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, with the exception of workers' compensation coverage for our employees. 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. □

As a public company, we are required to comply with significant legal, accounting, and other requirements and as such, have incurred significant regulatory compliance-related expenses. The Sarbanes-Oxley Act of 2002 as well as rules implemented by the Securities and Exchange Commission ("SEC") and NASDAQ, impose various requirements on public companies, including those related to corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Some members of management do not have significant experience in addressing these requirements. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to those of previous years and make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The Committee of Sponsoring Organizations of the Treadway Commission ("COSO") provides a framework for companies to assess and improve their internal control systems. Our compliance with these requirements has required that we incur substantial accounting and related expenses and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, are unable to assert that our internal controls over financial reporting are effective, or identify deficiencies that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC, or other regulatory authorities. Any of these events could have a material adverse effect on our business, financial position, and operating results.

Our ability to utilize the Company's or Dipexium'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 and any new tax law changes. □

Under Section 382 of the Internal Revenue Code of 1986, as amended, 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 the Company's and Dipexium's net operating loss and tax credit carryforwards may 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 the Company 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 know-how — 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.

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 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-parte 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. 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 UT. Our development and commercialization of Aspertec is subject to our license agreement with UT. 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, UT may have the right to terminate the applicable license in whole or in part. Specifically, Section 4.6 of our UT License Agreement provides that "Reasonable commercial diligence shall require that [the Company] . . . . [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, UT may have the option to terminate the UT License Agreement, or to limit the exclusivity of the license in certain territories.

The loss of our license agreement with UT 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 know-how 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 an 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 REMS 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 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 (which comprises the 28 member states of the European Union, 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 ACA 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 ACA, we expect that Aspertec will qualify for 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 ACA, 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

- HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, 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 ACA 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, sales and co-promotion arrangements outside the United States, we will be heavily regulated and expect to have significant interaction with foreign officials. The Company currently has indirect wholly owned subsidiaries in Chile and Ireland, which we are in process of dissolving. 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 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 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 December 31, 2017, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially owned approximately 37.3% 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.

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. Our $15.0 million term loan facility with Silicon Valley Bank limits our ability to pay dividends in certain circumstances. 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 may never publish research on us. If no securities or industry analysts commence coverage, the trading price for our stock would likely be negatively impacted. In the event one or more of the security or industry 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 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal facilities consist of office space in Houston, Texas and Sparta, New Jersey. In Houston, we occupy approximately 3,905 square feet of office and lab space, with rent of $5,727 per month, under a lease that expires December 31, 2019. In Sparta, we occupy approximately 2,463 square feet of office space, with rent of $5,542 per month, under a lease that expires September 30, 2021. In addition, we lease 5,006 square feet of office space in New York, New York from the former Dipexium headquarters with rent of $18,588 per month under a lease that expires July 31, 2021. We currently sublease the New York facility that generates income of $17,104 per month.

ITEM 3. 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.

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 2-1 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, in August 2017, the Third Circuit Appellate Court dismissed the case. Following such dismissal, we are no longer a named party to this suit.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock trades on the NASDAQ Capital Market under the symbol "PLXP." The following table sets forth the high and low sales prices per share of our common stock as quoted on the NASDAQ Capital Market for each quarter in the years ended December 31, 2017 and 2016, as adjusted for the one-for-eight reverse stock split that occurred on April 19, 2017:

	Common Stock Price			
	2017		2016	
	High	Low	High	Low
First Quarter	$ 14.00	$ 8.40	$ 97.84	$ 48.32
Second Quarter	$ 11.20	$ 5.60	$ 105.60	$ 68.32
Third Quarter	$ 7.35	$ 5.60	$ 142.00	$ 76.00
Fourth Quarter	$ 9.41	$ 6.10	$ 126.40	$ 9.20

Stockholder Information

As of March 1, 2018, there were approximately 285 holders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name.

Dividends

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. Our $15.0 million Term Loan Facility with SVB limits our ability to pay dividends in certain circumstances.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2017, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders	1,166,709	$ 18.54	242,903
Equity compensation plans not approved by stockholders	-	$ -	-
Total	1,166,709	$ 18.54	242,903

Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA.

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Statements in this Form 10-K 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 Part I, Item 1A, "Risk Factors" and in our consolidated financial statements and related notes, included 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. For further information regarding forward-looking statements, please refer to the "Information Regarding Forward-Looking Statements" at the beginning of Part I of this Form 10-K.

Our Management's Discussion and Analysis of Financial Condition and Results of Operations ("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.

Overview

We are a late-stage specialty pharmaceutical company initially focused on developing our clinically validated and patent-protected PLxGuard delivery system to provide more effective and safer 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 GI side effects — including erosions, ulcers and bleeding — associated with aspirin and ibuprofen, and potentially other drugs.

Our FDA-approved lead product, Aspertec 325 mg, is a novel formulation of aspirin using the PLxGuard delivery system that is intended to significantly reduce acute GI side effects while providing better 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 an sNDA, leveraging the already approved status of Aspertec 325 mg.

Our commercialization strategy will target both the 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 improved acute GI safety over regular aspirin, 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 aspirin product. Our product pipeline also includes other oral 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.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("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 Consolidated Financial Statements included elsewhere herein describes the significant accounting policies used in the preparation of our consolidated 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 our consolidated 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 consolidated 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, the fair value of warrant liabilities, share-based compensation, allowance for inventory obsolescence, allowance for doubtful accounts, contingent liabilities, fair value and depreciable lives of long-lived tangible and intangible 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. The fair value of the noncurrent term loan approximates its face value of $7,500,000 based on the Company's current financial condition and on the variable nature of term loan's interest feature as compared to current rates.

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.

Share-Based Compensation

The Company recognizes expense in the consolidated statements of operations for the fair value of all share-based compensation to key employees, nonemployee directors and advisors, generally in the form of stock options and stock awards. The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options 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 our consolidated financial statements.

Adopted Accounting Guidance

For a discussion of significant accounting guidance recently adopted or unadopted accounting guidance that has the potential of being significant, see Note 3 of the Notes to Consolidated Financial Statements included elsewhere herein.

Results of Operations

Revenue

Total revenues were $779,000 for the year ended December 31, 2017, as compared to $20,000 for the year ended December 31, 2016. Revenue recognized in fiscal year 2017 is attributable to work performed under a recent award of a National Institutes of Health grant, along with previously deferred revenue recognized upon the completion of effort.

Operating Expenses

Total operating expenses were approximately $16.6 million during the year ended December 31, 2017, a 244% increase over operating expenses of approximately $4.8 million during the year ended December 31, 2016. Operating expenses for the years ended December 31, 2017 and 2016 were as follows:

	Years Ended December 31,		Increase (Decrease)	
	2017	2016	$	%
Operating Expenses				
Research and development expenses	$ 4,157,454	$ 78,656	$ 4,078,798	5186%
General and administrative expenses	10,174,997	4,752,068	5,422,929	114%
Impairment charges	2,294,048	-	2,294,048	NM
Total operating expenses	$ 16,626,499	$ 4,830,724	$ 11,795,775	244%

Research and Development Expenses

Research and development expenses totaled approximately $4.2 million in the year ended December 31, 2017 compared to $0.1 million in the prior year, an increase of approximately $4.1 million. 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, initial clinical trial expenses and other product development activities for Aspertec throughout 2017.

General and Administrative Expenses

General and administrative expenses totaled approximately $10.2 million in the year ended December 31, 2017 compared to approximately $4.8 million in the prior year, an increase of approximately $5.4 million. The increase was primarily attributable to (i) increased compensation expense and outside directors fees of $2.2 million, including stock compensation expense, and (ii) other professional fees including legal, accounting, financial advisory, insurance and other administrative costs totaling approximately $1.8 million and expenses of $1.3 million allocated to the warrants issued in connection with the June 2017 equity offering.

Impairment Charges

In the fourth quarter of fiscal year 2017, the Company recognized impairment charges related to its intangible assets (trademarks and in-process research and development) acquired from Dipexium, in connection with a change in operational strategy related to its Locilex assets.

Other income (expense), net

Other income (expense), net totaled approximately $0.4 million of net expense in the year ended December 31, 2017 compared to $0.1 million of net expense in the prior year. The change is largely attributable to interest expense for our new credit facility (including the amortization of discounts and deferred issuance costs) of approximately $0.4 million, a beneficial conversion feature expense associated with the conversion of our convertible notes of $0.6 million, offset in part by the change in fair value of warrant liability of $0.6 million of other income.

Impact of the Tax Cuts and Jobs Act of 2017

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act of 2017 (the "Tax Act") which included significant changes to the existing income tax laws for domestic corporations. Key features of the Tax Act effective in 2018 include:

- Reduction of the corporate tax rate from 35% to 21%;
- Elimination of the alternative minimum tax;
- Changes in the deductibility of certain aspects of executive compensation;
- Changes in the deductibility of certain entertainment and recreation expenses; and
- Changes in incentive tax breaks for U.S production activities.

Because of the Company's existing Federal net operating loss carryforwards and current expectations as to the recovery of its net deferred tax assets, the Company believes that the Tax Act will not have a significant impact on its financial results and financial position, including on its liquidity, for the foreseeable future.

Liquidity and Capital Resources

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

(rounded to nearest thousand)	Years Ended December 31, 2017	2016
Net cash used in operating activities	$ (13,306,563)	$ (1,810,022)
Net cash provided by investing activities	$ 11,238,858	$ -
Net cash provided by financing activities	$ 26,412,738	$ 1,777,700

Net Cash Used in Operating Activities

Net cash used in operating activities of approximately $13.3 million for the year ended December 31, 2017 primarily reflects our net loss for the period of approximately $15.3 million adjusted for various non-cash charges and income, including (i) approximately $0.6 million change in fair value of warrant liability reflected as other income, (ii) net operating asset/liability changes of approximately $2.7 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 $1.6 million of equity based compensation, (vi) an impairment charge related to our acquired intangible assets of $2.3 million and (vii) approximately $0.6 million of noncash interest expense relating to a beneficial conversion feature.

Net cash used in operating activities of approximately $1.8 million for the year ended December 31, 2016 primarily reflects our net loss for the year of approximately $4.9 million adjusted for (i) approximately $2.5 million of non-cash stock based compensation expense and (ii) net operating asset/liability changes of approximately $0.6 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities totaled approximately $11.2 million in the year ended December 31, 2017 while the year ended December 31, 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 $0.5 million of equipment purchases.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled approximately $26.4 million in the year ended December 31, 2017 as compared to approximately $1.8 million in the year ended December 31, 2016. Net cash provided by financing activities in 2017 consisted of approximately $16.7 million of equity offering proceeds, $2.0 million pursuant to the note issued to Dipexium prior to the Merger, $7.1 million in net proceeds under a term loan from Silicon Valley Bank, and approximately $0.6 million of proceeds pursuant to a convertible note which subsequently converted to Old PLx equity immediately prior to the closing of the Merger. Net cash provided by financing activities in 2016 consisted solely of proceeds from the issuance of convertible notes.

Future Liquidity and Needs

As of December 31, 2017, we had working capital of approximately $23.9 million and cash and cash equivalents of approximately $24.4 million. Based on our expected operating cash requirements and capital expenditures, we believe the Company's cash on hand at December 31, 2017 is adequate to fund operations for at least twelve months from the date of filing of this Form 10-K.

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 December 31, 2017, we had an accumulated deficit of approximately $67.3 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 obtain 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 SVB that provides for the 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.

Inflation

The Company believes that the rates of inflation in recent years have not had a significant impact on its operations.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements as of December 31, 2017 or 2016.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and supplementary data required to be filed pursuant to this Item 8 are listed in Item 15 of this Form 10-K beginning on page F-1 and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Form 10-K, under the supervision and with the participation of management, including the Chief Executive Officer and the Chief Financial Officer of the Company (collectively, the "Certifying Officers"), the Company conducted an evaluation of its disclosure controls and procedures. As defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, the term "disclosure controls and procedures" means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under 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 by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including the Certifying Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, our Certifying Officers have concluded that, as of December 31, 2017, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company 's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel 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. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 with respect to future periods is 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.

Based on its evaluation of the Company's internal control over financial reporting as of December 31, 2017, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework (2013), our management has concluded that, as of December 31, 2017, our internal control over financial reporting was effective based on those criteria.

This Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Pursuant to Item 308(b) of Regulation S-K, management's report is not subject to attestation by our independent registered public accounting firm because the Company is neither an "accelerated filer" nor a "large accelerated filer" as those terms are defined by the SEC.

Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information required by this Item will be set forth in our definitive proxy statement for our 2018 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this Item will be set forth in our definitive proxy statement for our 2018 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this Item will be set forth in our definitive proxy statement for our 2018 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this Item will be set forth in our definitive proxy statement for our 2018 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this Item will be set forth in our definitive proxy statement for our 2018 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

Documents filed as part of this Form 10-K:

(a) Financial Statements:

The consolidated balance sheets of the Company as of December 31, 2017 and 2016, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years ended December 31, 2017 and 2016, the footnotes thereto, and the reports of GBH CPAs, PC, independent registered public accounting firm, are set forth on pages F-1 through F-19 of this Form 10-K.

(b) Exhibits:

See Exhibit Index.

(c) Financial Statement Schedules:

All schedules have been omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

PLx Pharma Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Changes in Stockholders' Equity (Deficit)	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
PLx Pharma Inc.
Houston, TX

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PLx Pharma Inc. (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GBH CPAs, PC

We have served as the Company's auditor since 2015.

GBH CPAs, PC
www.gbhcpas.com
Houston, Texas
March 23, 2018

PLx Pharma Inc.

CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 24,404,368	$ 59,335
Accounts receivable, net	19,384	5,077
Inventory, net	246,374	116,726
Vendor deposits	715,603	-
Prepaid expenses	300,169	4,652
Security deposit	4,064	4,064
TOTAL CURRENT ASSETS	25,689,962	189,854
NON-CURRENT ASSETS		
Property and equipment, net	1,029,875	426,634
Goodwill	2,061,022	-
Security deposit	67,714	-
TOTAL ASSETS	$ 28,848,573	$ 616,488
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 852,155	$ 862,995
Accrued bonus and severance	849,703	-
Accrued interest	54,219	64,781
Accrued interest – related parties	-	30,344
Convertible notes payable	-	1,297,700
Convertible notes payable – related parties	-	480,000
Other current liabilities	59,614	-
TOTAL CURRENT LIABILITIES	1,815,691	2,735,820
NON-CURRENT LIABILITIES		
Deferred revenue	-	200,000
Accrued interest, net of current portion	89,717	-
Term loan, net of discount and deferred issuance costs	6,942,151	-
Warrant liability	15,242,915	-
Other liabilities	141,707	-
TOTAL LIABILITIES	24,232,181	2,935,820
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY (DEFICIT)		
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; 8,722,823 and 4,383,433 shares issued and outstanding, respectively	8,723	4,383
Additional paid-in capital	71,939,917	49,661,802
Accumulated deficit	(67,332,248)	(51,985,517)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	4,616,392	(2,319,332)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 28,848,573	$ 616,488

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2017	**2016**
REVENUES:		
Federal grants	$ 578,657	$ -
License revenue	200,000	20,000
TOTAL REVENUES	778,657	20,000
OPERATING EXPENSES:		
Research and development	4,157,454	78,656
General and administrative	10,174,997	4,752,068
Impairment of intangible assets	2,294,048	-
TOTAL OPERATING EXPENSES	16,626,499	4,830,724
OPERATING LOSS	(15,847,842)	(4,810,724)
OTHER INCOME (EXPENSE)		
Interest income	112,377	571
Interest expense	(1,164,897)	(95,125)
Change in fair value of warrant liability	633,631	-
TOTAL OTHER INCOME (EXPENSE)	(418,889)	(94,554)
LOSS BEFORE INCOME TAX BENEFIT	(16,266,731)	(4,905,278)
Income tax benefit	920,000	-
NET LOSS	$ (15,346,731)	$ (4,905,278)
Net loss per common share - basic and diluted	$ (2.19)	$ (1.12)
Weighted average common shares outstanding - basic and diluted	7,020,479	4,383,433

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.

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, 2015	-	$ -	4,383,433	$ 4,383	$47,190,013	$ (47,080,239)	$ 114,157
Stock-based compensation expense					2,471,789		2,471,789
Net loss						(4,905,278)	(4,905,278)
Balance at December 31, 2016	-	$ -	4,383,433	$ 4,383	$49,661,802	$ (51,985,517)	$ (2,319,332)
Stock-based compensation expense			30,000	30	1,624,381		1,624,411
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	-	-	9,347	10	60,109		60,119
Term loan proceeds allocated to warrants					304,201		304,201
Net loss						(15,346,731)	(15,346,731)
Balance at December 31, 2017	-	$ -	8,722,823	$ 8,723	$71,939,917	$ (67,332,248)	$ 4,616,392

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (15,346,731)	$ (4,905,278)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and impairments	29,838	3,325
Share-based compensation	1,624,411	2,471,789
Impairment expense	2,294,048	-
Noncash interest expense	724,676	-
Change in fair value of warrant liability	(633,631)	-
Expenses allocated to warrant liability	1,302,995	-
Provision for obsolete inventory	319,736	-
Deferred tax benefit	(920,000)	-
Changes in operating assets and liabilities:		
Accounts receivable	(14,307)	(5,077)
Inventory	(449,384)	(116,726)
Vendor deposits	(715,603)	-
Prepaid expenses and other assets	(223,583)	13,794
Accounts payable and accrued liabilities	(109,644)	633,026
Accrued bonus and severance	(1,434,297)	-
Accrued interest	229,845	64,781
Accrued interest - related parties	13,747	30,344
Deferred revenue	(200,000)	-
Other liabilities	201,321	-
Net cash used in operating activities	(13,306,563)	(1,810,022)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(537,569)	-
Cash received in business combination	11,776,427	-
Net cash provided by investing activities	11,238,858	-
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of convertible notes payable	460,000	1,297,700
Proceeds from issuance of convertible notes payable - related parties	108,300	480,000
Proceeds from Dipexium note	2,000,000	-
Proceeds from issuance of term loan and warrants, net of allocated issuance costs	7,145,584	-
Proceeds from equity offering, net of allocated issuance costs	16,698,854	-
Net cash provided by financing activities	26,412,738	1,777,700
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	24,345,033	(32,322)
Cash and cash equivalents, beginning of year	59,335	91,657
Cash and cash equivalents, end of year	$ 24,404,368	$ 59,335
SUPPLEMENTAL INFORMATION		
Cash paid during the year for:		
Income taxes	$ -	$ -
Interest	$ 195,938	$ -
NON-CASH INVESTING AND FINANCING TRANSACTIONS		
Property and equipment included in accounts payable	$ 89,558	$ -
Value of common shares issued to vendors for services	$ 60,119	$ -
Equity offering proceeds allocated to warrant liability	$ 15,876,546	$ -
Term loan proceeds allocated to warrants	$ 304,201	$ -
Issuance of common shares for business combination	$ 15,048,883	$ -
Issuance of common shares upon conversion of debt and accrued interest	$ (2,495,630)	$ -

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2017

NOTE 1. BACKGROUND AND ORGANIZATION

Business Operations
PLx Pharma Inc. (the "Company"), together with its subsidiaries PLx Opco Inc., PLx Chile SpA and Dipexium Pharmaceuticals Ireland Limited, 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 filled aspirin capsule.

PLx Chile SpA was formed on September 12, 2011 as a wholly-owned subsidiary of PLx Opco Inc. Dipexium Pharmaceuticals Ireland Limited was formed on August 16, 2016 as a wholly owned subsidiary of Dipexium Pharmaceuticals.

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, renamed 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 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 our expected operating cash requirements and capital expenditures, we believe the Company's cash on hand at December 31, 2017, including the cash resources obtained (i) in the Merger, (ii) from the equity financing completed in June 2017 and (iii) from the debt financing completed in August 2017, is adequate to fund operations for at least twelve months from the date that these financial statements were issued.

NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis and Accounting and Principles of Consolidation
The Company prepares its consolidated financial statements in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The Company operates in one business segment.

The accompanying consolidated financial statements include the accounts of the Company and its direct and indirect wholly-owned subsidiaries, PLx Opco Inc., PLx Chile SpA and Dipexium Pharmaceuticals Ireland Limited. All significant intercompany balances and transactions have been eliminated within the 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, the fair value of warrant liabilities, share-based compensation, our allowance for inventory obsolescence, our allowance for doubtful accounts, contingent liabilities, the fair value and depreciable lives of long-lived tangible and intangible assets, and deferred taxes and the associated valuation allowance. Actual results could differ from those estimates.

Foreign Currency
The functional currency of our international subsidiaries 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 December 31, 2017, the Company had cash and cash equivalents of approximately $24.4 million in U.S. bank accounts which were not fully insured by the Federal Deposit Insurance Corporation.

Allowance for Uncollectible 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 December 31, 2017 and 2016, respectively.

Inventory
Inventory is stated at the lower of cost or net realizable value, using the average cost method. Inventory as of December 31, 2017 and 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 $320,000 and $0 as of December 31, 2017 and 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. The fair value of the noncurrent term loan approximates its face value of $7,500,000 based on the Company's current financial condition and on the variable nature of the term loan's interest feature as compared to current rates. For disclosures concerning fair value measurements, see Note 9.

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. See Note 5 for a discussion of the Company's impairment analysis for 2017.

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 to 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. See Note 5 for a discussion of the Company's impairment analysis for 2017.

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. See Note 5 for a discussion of the Company's impairment analysis for 2017.

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's revenue in 2017 and 2016 was generated pursuant to 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 uses 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.

Share-Based Compensation
The Company recognizes expense in our consolidated statements of operations for the fair value of all share-based compensation to key employees, nonemployee directors and advisors, generally in the form of stock options and stock awards. The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options 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 share-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
Income 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. Corporate tax rate changes resulting from the impacts of the Tax Cuts and Jobs Act of 2017 (the "Tax Act") are reflected in deferred tax assets and liabilities as of December 31, 2017 since the Tax Act was enacted in December 2017. 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.

The Company is no longer subject to U.S. Federal or state examinations by tax authorities for years ending before December 31, 2011.

Reverse Stock Split

The Company's 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.

Earnings (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 shares underlying 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 common shares underlying (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 3,871,302 shares and 872,772 shares as of December 31, 2017 and 2016, respectively.

Recent Accounting Developments

Recently Adopted Guidance

In March 2016, the Financial Accounting Standards Board (the "FASB") issued guidance simplifying the accounting for, and financial statement disclosure of, share-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 share-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 price 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 year ended December 31, 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 finalizing its evaluation of the impact that this guidance will have on its consolidated financial statements. Because the Company does not have existing significant revenue arrangements with unfulfilled performance obligations, management currently 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., PLx Chile SpA and Dipexium Pharmaceuticals Ireland Limited, 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		(2,045,151)
Total purchase consideration	$	13,003,732

The Company recorded all tangible and intangible assets acquired and liabilities assumed at their estimated fair values on the Merger date. The following represents the allocation of the 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)
Fair value of liabilities assumed		(2,353,365)
	$	13,003,732

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. See Note 5 for a discussion of the Company's impairment assessment of the acquired intangible assets.

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 net 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 years ended December 31, 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	Year Ended December 31, 2017	Year Ended December 31, 2016
Revenues	$ 778,657	$ 20,000
Net loss	$ (16,776,931)	$ (26,145,568)
Net loss per share	$ (2.23)	$ (4.33)

NOTE 5. LONG-LIVED ASSETS

Property and Equipment
Property and equipment at December 31, 2017 and 2016 consisted of the following:

Asset Descriptions	Useful Lives (years)	December 31, 2017	December 31, 2016
Computer equipment	4	$ 41,839	$ 41,839
Lab equipment	5	8,655	8,655
Office equipment, furniture and fixtures	5	18,302	18,302
Leasehold improvements	lease term	10,088	-
Manufacturing equipment	7	1,400,114	783,075
Subtotal		1,478,998	851,871
Less: Accumulated depreciation		(91,123)	(67,237)
Less: Impairment		(358,000)	(358,000)
Total property and equipment, net		$ 1,029,875	$ 426,634

Depreciation for the years ended December 31, 2017 and 2016 was $23,886 and $3,325, respectively.

In early 2014, management decided to sell certain manufacturing equipment that had not been placed in service. The equipment had an aggregate historical cost of $783,075. Based on estimated cash flows from the potential sale of the equipment, an impairment loss of $358,000 was recorded during the year ended December 31, 2013. Management withdrew the equipment from sale and plans to start using and depreciating the equipment during the initiation of pre-commercialization manufacturing activities in 2017.

Goodwill and Intangible Assets
We established goodwill and other intangible assets in 2017 in connection with the Merger. Our goodwill and other intangible assets as of December 31, 2017 are as follows:

Trademarks (definite-lived)	$ 100,000
IPR&D (indefinite-lived)	2,200,000
Goodwill (indefinite-lived)	2,061,022
	4,361,022
Less: Accumulated amortization trademarks	(5,952)
Less: Impairment – trademarks and IPR&D	(2,294,048)
Total goodwill and intangible assets, net	$ 2,061,022

The Company's intangible asset for trademarks was related to the Locilex brand acquired from Dipexium. After assessing its resources and corporate strategy in November 2017, the Company has decided that it will no longer pursue the development of additional indications for Locilex and will instead focus all of its efforts and resources on the successful commercialization of Aspertec. As a result of this decision, the Company has decided to take the following actions with respect to Locilex:

- submit paperwork to the FDA to put the Pexiganan IND in an inactive status;
- abandon the DPRX domain;
- terminate the facility storage contract with a third party vendor and destroy existing active pharmaceutical ingredient product; and
- cease paying patent renewal fees, allowing patents to expire.

As a result of the strategic change not to pursue further development of Locilex, the Company believes that its IPR&D is impaired as of October 31, 2017 and that the IPR&D had zero fair value as of that date. The Company recognized an impairment loss in the fourth quarter of $2.2 million. Additionally, the Company believes that its trademarks asset is impaired as of October 31, 2017 and that the trademarks asset had a zero fair value as of that date. The Company recognized an impairment loss in the fourth quarter of approximately $0.1 million (carrying value).

The Company has not identified any events or changes in circumstances that indicate that a potential impairment of goodwill occurred as of October 31, 2017. As such, the Company believes goodwill is not impaired.

NOTE 6. DEBT

Term Loan Facility

On August 9, 2017, the Company entered into 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 (8.50% at December 31, 2017), 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 final payment fee is being accrued using the effective interest method over the period of the Term Loan Facility.

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, stock purchase warrants to purchase an aggregate of 58,502 shares of the Company's common stock at an exercise price of $6.41 per share. The warrants are immediately exercisable, have a 10-year term, contain a cashless exercise provision, and are classified in equity. The relative fair value of the warrants, net of issuance costs, was $304,201.

As of December 31, 2017, the $7.5 million face value of the Term Loan was presented in the accompanying consolidated balance sheet net of unamortized discounts and issuance costs of $557,849.

Convertible Notes Payable and Convertible Notes Payable – Related Parties

During 2016 and during the 2017 period prior to the Merger, the Company borrowed $2,346,000 from a number of 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 as a maturity date the later of (a) October 15, 2017, or (b) the date that would have been 270 days following the termination of the Merger Agreement, subject to acceleration in the event that the Merger Agreement had been 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 were eliminated in consolidation.

NOTE 7. 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 liability classified due to certain cash settlement provisions.

Stock Options

Following is a summary of option activities for the years ended December 31, 2017 and 2016:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2015	691,374	$ 12.44	8.62	$ -
Outstanding, December 31, 2016	691,374	$ 12.44	8.62	$ -
Granted	283,372	$ 6.75		
Options from Dipexium	191,963	$ 57.94		
Cancelled	-			
Outstanding, December 31, 2017	1,166,709	$ 18.54	7.84	$ 90,097
Exercisable, December 31, 2017	888,124	$ 21.71	7.48	$ 15,637

The Company has granted 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 date of the Merger that continue to be exercisable. At December 31, 2017, an aggregate of 242,903 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 scheduled to vest on the closing date of a contemplated 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 year ended December 31, 2017, the Company granted total stock options to purchase a total of 283,372 common shares to employees at a weighted average strike price of $6.75 per share. The options had an aggregate fair value of approximately $1.3 million, which was calculated using the Black-Scholes model on the grant date. Variables used in the Black-Scholes model include: (1) discount rates of 1.2%-2.1%, (2) expected lives of 4.7 – 8.0 years, (3) expected volatility of approximately 75%-86%, and (4) zero expected dividends.

As of December 31, 2017, the Company had $1.4 million in unamortized expense related to unvested options which is expected to be expensed over a weighted average of 1.9 years.

The Company modified certain outstanding awards to a former officer upon his termination of employment, and recognized approximately $150,000 of expense in the third quarter 2017 related to such modification. The Company also recognized approximately $200,000 in the third quarter of 2017 related to an officer's bonus that was settled in 30,000 shares of common stock.

During the years ended December 31, 2017 and 2016, the Company recorded $1,624,411 and $2,471,789, respectively, in total compensation expense related to the stock options and stock bonuses. For the year ended December 31, 2017, $1,623,056 of stock-based compensation expense is classified as general and administrative expenses and $1,355 is classified as research and development expenses in the accompanying consolidated statements of operations.

NOTE 8. COMMITMENTS AND CONTINGENCIES

Lease Agreement

The Company presently leases office space under operating lease agreements, expiring on December 31, 2019, July 31, 2021 and October 3, 2021, respectively. The office leases require the Company to pay for its portion of taxes, maintenance and insurance. Rental expense under these agreements was $175,552 and $62,349 for the years ended December 31, 2017 and 2016, respectively.

Future minimum obligations under non-cancelable operating leases are:

2018	$	343,144
2019		349,804
2020		301,993
2021		190,874
Total	$	1,185,815

The Company ceased using the office space under one of the leases in the fourth quarter of 2017 and entered into a sublease agreement that leases substantially all of the space to a subtenant; the Company recognized a loss of abandonment of approximately $200,000 in the fourth quarter of 2017 related to the abandonment. The above table of minimum lease payments excludes approximately $784,000 of sublease payments expected to be received through July 31, 2021.

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. The Development and Commercialization Agreement was terminated in its entirety in the fourth quarter of 2017 and, as a result, the Company recognized the entire $200,000 of non-refundable royalties as revenue in the fourth quarter of 2017.

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 three projects are estimated to cost $2.8 million, and in 2017 the Company paid a total of $1,237,750 as deposits for project initiation. As of December 31, 2017, the remaining unused deposit was $445,625.

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 9,347 common shares in 2017 as payment for services for May through December 2017.

Severance Obligations
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 payments of $12,500 for twelve months following the separation date. Accordingly, the Company expensed $150,000 of severance related to this arrangement in the third quarter of 2017 and has approximately $87,500 accrued and unpaid as of December 31, 2017.

NOTE 9. 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 subjective determinations regarding 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, 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 year ended December 31, 2017:

Description	Balance at December 31, 2016	Established in 2017	Change in Fair Value	Balance at December 31, 2017
Warrant liability	$ -	$ 15,876,546	$ (633,631)	$ 15,242,915

The following table identifies the carrying amounts of such liabilities at December 31, 2017:

	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 15,242,915	$ 15,242,915
Balance at December 31, 2017	$ -	$ -	$ 15,242,915	$ 15,242,915

The Company had no financial assets or 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 or 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 or 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. The Company recognized total impairment expenses related to its trademarks and IPR&D of $2,294,048 in the fourth quarter of 2017. No impairment expense was recognized in 2016.

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

NOTE 10. INCOME TAXES
Income tax (expense) benefit for the years ended December 31, 2017 and 2016 consisted of the following:

	Year Ended December 31, 2017	Year Ended December 31, 2016
Current:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Deferred:		
Federal	12,770,584	1,551,284
State	-	-
Foreign	-	-
Change in valuation allowance	(13,690,584)	(1,551,284)
Total Benefit for Income Taxes	$ (920,000)	$ -

The income tax benefit of $920,000 for the year ended December 31, 2017 relates to the basis difference in the acquired intangible assets acquired from Dipexium.

Significant components of the Company's deferred tax assets and liabilities consisted of the following at December 31, 2017 and 2016:

	December 31, 2017	December 31, 2016
Deferred tax assets:		
Stock-based compensation	$ 3,085,484	$ 922,463
Tax credit carryforwards	3,616,246	-
Net operating loss carryforwards	8,715,591	833,458
Intangible assets	372,944	604,416
Other	350,690	81,111
Total deferred tax assets	16,140,955	2,441,448
Deferred tax liabilities:		
Property and equipment	8,922	-
Total deferred tax liabilities	8,922	-
Net deferred tax assets	16,132,033	2,441,448
Less valuation allowance	(16,132,033)	(2,441,448)
Total deferred tax assets (liabilities)	$ -	-

The following table presents reconciles the U.S. federal statutory income tax rate in effect for 2017 and the Company's effective tax rate:

	Year Ended December 31, 2017	Year Ended December 31, 2016
U.S. federal statutory income tax	(34.0%)	(34.0%)
State and local income tax, net of benefits	-	-
Fair value of derivatives	(1.40%)	-
Release of valuation allowance in connection with merger	5.99%	-
Tax rate changes and other	37.85%	0.69%
Valuation allowance for deferred income tax assets	(2.44%)	33.31%
Effective income tax rate	(6.00%)	0.0%

The reduction in the federal tax rate to 21% under the Tax Act, effective on January 1, 2018, resulted in a reduction in the value of the Company's net deferred tax assets and related valuation allowance of approximately $5.9 million. The Company had net operating loss carry-forwards of approximately $41.5 million as of December 31, 2017, that may be offset against future taxable income. The carry-forwards will begin to expire in 2035. Use of these carry-forwards may be subject to annual limitations based upon previous significant changes in stock ownership. The Company does not believe that it has any uncertain income tax positions.

 Exhibit Index

The representations and warranties contained in the agreements listed in this Exhibit Index are not for the benefit of any party other than the parties to such agreement and are not intended as a document for investors or the public generally to obtain factual information about the Company or its shares of common stock.

Number	Exhibit Table
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	Amended and Restated Certificate of Incorporation of PLx Pharma Inc. (incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36351)).
3.2	Amended and Restated Bylaws of PLx Pharma Inc. (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K filed on January 20, 2017) (File No. 001-36351)).
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)).
4.2	Form of Warrant to Purchase Common Stock issued by PLx Pharma Inc. in connection with the Loan and Security Agreement among PLx Pharma Inc., PLx Opco Inc., and Silicon Valley Bank, dated as of August 9, 2017 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on August 10, 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. Jorden, 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	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)).
10.6	Separation and Settlement Agreement and Release of All Claims between PLx Pharma Inc. and David E. Jorden, 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)).
10.7	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	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)).

10.9	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)).
10.10	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)).
10.11	Loan and Security Agreement among PLx Pharma Inc., PLx Opco Inc., and Silicon Valley Bank, dated as of August 9, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 10, 2017 (File No. 001-36351)).
10.12	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)).
10.13	Amendment to Amended and Restated Employment Agreement of Gary Mossman, effective as of September 15, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 19, 2017 (File No. 001-36351)).
21.1	Subsidiaries of the Company.*
23.1	Consent of GBH CPAs, PC.*
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 and 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.*
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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PLx Pharma Inc.

By: /s/ Natasha Giordano
Natasha Giordano
President and Chief Executive Officer
(principal executive officer)

Date: March 23, 2018

By: /s/ Rita O'Connor
Rita O'Connor
Chief Financial Officer
(principal financial and accounting officer)

Date: March 23, 2018

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Natasha Giordano and Rita O'Connor, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ Natasha Giordano Natasha Giordano	Director, President and Chief Executive Officer	March 23, 2018
/s/ Michael J. Valentino Michael J. Valentino	Director and Executive Chairman of the Board	March 23, 2018
/s/ Gary Balkema Gary Balkema	Director	March 23, 2018
/s/ Robert Casale Robert Casale	Director	March 23, 2018
/s/ Kirk Calhoun Kirk Calhoun	Director	March 23, 2018
/s/ John W. Hadden II John W. Hadden II	Director	March 23, 2018

Exhibit 21.1

Subsidiaries of PLx Pharma Inc.

1. PLx Opco Inc., organized under the laws of Delaware
2. PLx Chile SpA, organized under the laws of Chile
3. Dipexium Pharmaceuticals Ireland Limited, organized under the laws of Ireland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement No. 333-204830 on Form S-3 and Registration Statements No. 333-196824 and 333-212421 on Form S-8 of PLx Pharma, Inc. (formerly Dipexium Pharmaceuticals, Inc.) of our report dated March 23, 2018 relating to the consolidated financial statements of PLx Pharma, Inc. as of December 31, 2017 and 2016 and for each of the years then ended, which report is included in the Annual Report on Form 10-K of PLx Pharma, Inc. for the year ended December 31, 2017.

/s/ GBH CPAs, PC

GBH CPAs, PC
www.gbhcpas.com
Houston, Texas

March 23, 2018

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Natasha Giordano, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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 consolidated subsidiaries, 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 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 (or persons performing the equivalent functions):

   (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: March 23, 2018

/s/ Natasha Giordano
Natasha Giordano
President and
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rita O'Connor, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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 consolidated subsidiaries, 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 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 (or persons performing the equivalent functions):

   (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: March 23, 2018

/s/ Rita O'Connor
Rita O'Connor
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of PLx Pharma Inc. (the "Company") for the year ended December 31, 2017 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(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 operations of the Company.

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Dated: March 23, 2018

/s/ Natasha Giordano
Natasha Giordano
President and
Chief Executive Officer
(principal executive officer)

Dated: March 23, 2018

/s/ Rita O'Connor
Rita O'Connor
Chief Financial Officer
(principal financial officer)

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.