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, 2019
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.)
9 Fishers Lane, Suite E **Sparta, NJ**	**07871**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: **(973) 409-6541**

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

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	PLXP	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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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 28, 2019 (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 $62.4 million.

As of March 10, 2020, there were 9,156,260 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 2020 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**	19
ITEM 1B.	**UNRESOLVED STAFF COMMENTS**	40
ITEM 2.	**PROPERTIES**	40
ITEM 3.	**LEGAL PROCEEDINGS**	40
ITEM 4.	**MINE SAFETY DISCLOSURES**	40

PART II

ITEM 5.	**MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**	40
ITEM 6.	**SELECTED FINANCIAL DATA**	41
ITEM 7.	**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**	41
ITEM 7A.	**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**	45
ITEM 8.	**FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**	46
ITEM 9.	**CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**	46
ITEM 9A.	**CONTROLS AND PROCEDURES**	46
ITEM 9B.	**OTHER INFORMATION**	47

PART III

ITEM 10.	**DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**	47
ITEM 11.	**EXECUTIVE COMPENSATION**	47
ITEM 12.	**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**	47
ITEM 13.	**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**	47
ITEM 14.	**PRINCIPAL ACCOUNTING FEES AND SERVICES**	47

PART IV

ITEM 15.	**EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**	47
ITEM 16.	**FORM 10-K SUMMARY**	
		47

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, VAZALORE 81 mg and 325 mg, to market-readiness;
- our ability to maintain regulatory approval of VAZALORE 325 mg or obtain and maintain regulatory approval of VAZALORE 81 mg and any future product candidates;
- the benefits of the use of VAZALORE;
- 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 VAZALORE products, or any future product candidates;
- the rate and degree of market acceptance of our VAZALORE 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 VAZALORE 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 VAZALORE 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 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®
- PLX PHARMA®
- PLXGUARD™
- VAZALORE™
-  ™
- FIRST LIQUID-FILLED ASPIRIN CAPSULES™
- 

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 focused on developing our clinically-validated and patent-protected PLxGuard delivery system to provide more effective and safer products. Our PLxGuard delivery system works by targeting the release of active pharmaceutical ingredients to various portions of the GI tract. We believe this has the potential to improve the absorption of many drugs currently on the market or in development, and to reduce the risk of stomach erosions, ulcers and bleeding associated with aspirin and ibuprofen, and potentially other drugs.

The U.S. Food and Drug Administration ("FDA") approved our lead product, VAZALORE 325 mg, which is a novel formulation of aspirin using the PLxGuard delivery system intended to provide better antiplatelet effectiveness for vascular disease prevention and treatment as compared to the current standard of care, enteric-coated aspirin, and significantly reduce gastric side effects as compared with immediate-release aspirin. VAZALORE 325 mg (formerly PL2200 Aspirin 325 mg and Aspertec 325 mg) was originally approved under the drug name aspirin, and the proprietary name 'VAZALORE' was granted subsequent to the FDA approval. A companion 81 mg dose of the same novel formulation, VAZALORE 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 VAZALORE 325 mg. We are focused on collecting the data, including initiating a bioequivalence study, required for post-approval manufacturing changes which will be included in the sNDA filing for VAZALORE 325 mg and to support approval of low dose VAZALORE 81 mg. The Company will be able to better assess the timing of its product launch once the sNDA filings has been submitted.

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 VAZALORE 325 mg and anticipated approval for VAZALORE 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 GI safety, we intend to market VAZALORE to the health care professional and the consumer through several marketing channels including a physician-directed sales force. 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 with a targeted release to select 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 utilizes both the differential pH in the GI tract and the presence of bile acid bicarbonate and pancreatic enzymes in the duodenum to target VAZALORE's release. This approach is intended to more reliably and precisely 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 bioavailability and 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 shown 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, VAZALORE 325 mg, has been approved by the FDA for OTC distribution and is the first-ever FDA-approved liquid-filled aspirin capsule.. In clinical trials in diabetic patients at risk for cardiovascular disease, VAZALORE 325 mg demonstrated better antiplatelet efficacy than enteric-coated aspirin, which is the current standard of care for cardiovascular disease prevention and treatment. VAZALORE 325 mg delivers faster and more reliable absorption 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. Near complete inhibition of serum Thromboxane B2 (>99%) is a clinically accepted marker for antiplatelet efficacy, which is sometimes referred to as aspirin response. VAZALORE 325 mg has more reliable and predictable bioavailability resulting in 5 times greater aspirin absorption versus enteric-coated aspirin after 3 days of treatment. This greater bioavailability translates into consistent and sustained antiplatelet benefits with twice as many patients achieving a complete antiplatelet response after 3 days treatment compared with enteric-coated aspirin. The faster and more reliable platelet inhibition achieved with VAZALORE 325 mg may be particularly important in the hospital management of acute vascular events such as heart attacks and strokes where platelet inhibition is absolutely critical, but also for the long-term protection from recurrent events. VAZALORE 325 mg has also demonstrated reduced risk for stomach erosions, ulcerations and bleeding compared with immediate release aspirin with statistically significant 71% reduction in the risk for ulcers in healthy subjects in an acute setting. The lower risk for GI complications can have important benefits including better drug tolerance for the patients (less dyspepsia, bloating, etc.), less use of stomach acid reducers (antacids, proton pump inhibitors, etc.) and lower risk for gastric bleeding. The reduction of adverse gastric events may also be particularly important in the hospital setting where patients with acute vascular events such as heart attacks and strokes are at very high risk for gastric bleeding due to the stress associated with the episode and the co-administration of other blood thinners (i.e. heparin) that are standard components of the treatment protocols. Finally, the gastric safety benefit may also be used to differentiate VAZALORE 325 mg from products intended for use in conditions associated with pain and inflammation, including other aspirin and NSAID products.

VAZALORE 81 mg is our lower-dose companion product for VAZALORE 325 mg (the two dose forms are sometimes referred to in this Form 10-K together as “VAZALORE”). 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 are focused on collecting the data, including initiating a bioequivalence study, required for post-approval manufacturing changes which will be included in the sNDA filing for VAZALORE 325 mg and to support approval of low dose VAZALORE 81 mg. The Company will be able to better assess the timing of its product launch once the sNDA filings has been submitted.

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 tolerability 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 VAZALORE and other product candidates. We have entered into a Manufacturing Services Agreement with Thermo Fisher Scientific’s Pharma Services (“Thermo Fisher”) business to provide the capabilities to bring VAZALORE to market. We currently employ internal resources to manage our manufacturing contractors. Our agreement with Thermo Fisher includes representations and warranties that Thermo Fisher will perform its services under the agreement in compliance with current Good Manufacturing Practices (“cGMP”). There can be no assurance that VAZALORE 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 current Good Laboratory Practices (“cGLPs”) 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.

While we believe that most of the ingredients we require to manufacture VAZALORE are readily available from multiple suppliers and are commonly used in the pharmaceutical industry, some key components are sourced from a limited number of suppliers.

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.

VAZALORE 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 Genus Lifesciences, Inc. (Yosprala) and Espero BioPharma, Inc. (Durlaza) that are to the best of our knowledge not currently marketed in the US. 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. VAZALORE 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). VAZALORE 325 mg is the only liquid-filled aspirin capsule product to be approved by the FDA. VAZALORE 325 mg went through a different regulatory approval process than the current OTC aspirin products being marketed in the US. VAZALORE 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 VAZALORE 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 VAZALORE, 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 23 issued patents in other jurisdictions expiring on December 19, 2021, and one pending patent application in Brazil.

- *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 VAZALORE 325 mg and 81 mg, other NSAID products and will broaden the opportunity for new products to include many different drug classes. In the United States we have four patents issued 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, 9730884, and 10179104 expiring on September 29, 2032, in China issued number ZL201280058596X expiring on September 28, 2032, in Hong Kong issued number HK1200098 expiring September 29, 2032, in Australia issued number 2012315545 expiring September 29, 2032 and in Mexico we have issued patents numbered 340951 and 356017 expiring on September 29, 2032. We have also received a Notice of Allowance in Japan. We have pending applications in Europe, Canada, India, and South Korea and in the United States and Japan for additional claims which, if issued, are expected to provide patent protection through September 29, 2032.

U.S. patent numbers 8865187 and 9351984 with "*Compositions comprising lecithin oils and NSAIDs for protecting the gastrointestinal tract and providing enhanced therapeutic activity*", U.S. patent number 9101637 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 VAZALORE 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. 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 VAZALORE, 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 UT License Agreement is in effect as long as the patents are valid and we may terminate the UT License 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 UT License Agreement, or to limit the exclusivity of the license in certain territories. The UT License 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 UT License 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.

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 documentation of the manufacturing process and accompanying quality control system intended for raw materials, in-process materials, and the finished dosage form suitable for administration;
- 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 eligible 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 VAZALORE 325 mg is commercialized, we believe it will be the only NDA-approved OTC aspirin product available. Approval of the VAZALORE NDA granted VAZALORE 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.

Products	**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, 2019, we had 12 employees, of which 10 are full time employees. Of these full-time employees, two work on research and development, and clinical operations and eight 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 9 Fishers Lane, Suite E, Sparta, NJ 07871, and our telephone number is (973) 409-6541. 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 operating 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 grant activities, and have incurred operating losses since we commenced operations. The Company's operating loss for the year ended December 31, 2019 was $14.2 million. As of December 31, 2019, we had an accumulated deficit of approximately $86.9 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 VAZALORE 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 VAZALORE and any other product candidates for which we may obtain marketing approval;
- establish a manufacturing and supply chain sufficient for commercial quantities of VAZALORE 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, 2019, we had working capital of approximately $8.2 million and cash and cash equivalents of approximately $14.0 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 had the right to borrow an additional $7.5 million on or before December 31, 2018, provided that the Company first obtained (a) net new capital of not less than $20,000,000 and (ii) FDA approval for the 81 mg formulation of VAZALORE, the Company's lead product. The Company did not satisfy the requirements for the additional $7.5 million by the December 31, 2018 deadline. On December 20, 2018, the Company entered into a Purchase Agreement (the "Purchase Agreement") pursuant to which the Company agreed to issue 15,000 shares of Series A Convertible Preferred Stock to certain investors for gross proceeds of $15 million, subject to stockholder approval which was received on February 19, 2019, and the financing was completed on February 20, 2019 (the "Private Placement").

In March 2019, we entered into an equity distribution agreement (the "Equity Distribution Agreement") with JMP Securities LLC ("JMP") to issue and sell shares of our common stock, having an aggregate offering price of up to $12.5 million, from time to time during the term of the Equity Distribution Agreement, through an "at-the-market" equity offering program at our sole discretion, under which JMP will act as our agent. The Company will pay JMP a commission of 3.0% of the gross proceeds from each sale of shares pursuant to the Equity Distribution Agreement, reimburse legal fees and disbursements and provide JMP with customary indemnification and contribution rights. As of December 31, 2019, we had sold approximately $2.3 million of shares of our common stock pursuant to the Equity Distribution Agreement on a gross basis. However, there can be no assurance that JMP will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Equity Distribution Agreement, is limited to an aggregate of one-third of our public float. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. In addition, JMP is permitted to terminate the Equity Distribution Agreement in its sole discretion upon one day notice, or at any time in certain circumstances, including the occurrence of a material adverse change in the Company's business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares.

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, VAZALORE. If we are unable to successfully commercialize VAZALORE 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 VAZALORE, which will depend on several factors, including the following:

- Establishing and maintaining commercial manufacturing and supply arrangements;
- establishing and maintaining a commercial infrastructure;
- identifying and successfully establishing one or more collaborations to commercialize VAZALORE;
- 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 VAZALORE 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, VAZALORE 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 VAZALORE 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 VAZALORE 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 VAZALORE, 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 VAZALORE 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 VAZALORE 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 VAZALORE 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 VAZALORE from other aspirin products in the market, we may not be able to make direct comparative claims regarding the safety or efficacy of VAZALORE and other aspirin products in our promotional materials for VAZALORE. Any failure by VAZALORE 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 VAZALORE 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, VAZALORE 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 VAZALORE 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.

We will rely on third-party contract manufacturing organizations to manufacture and supply VAZALORE 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 VAZALORE. 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 VAZALORE 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 have entered into a Manufacturing Services Agreement with Thermo Fisher's Pharma Services business, to provide the capabilities to bring VAZALORE to market. We do not have commercial supply agreements with all of our raw material 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.

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 VAZALORE or future product candidates;
- decreased demand for VAZALORE 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 VAZALORE 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 VAZALORE. 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 VAZALORE 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 VAZALORE 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, 2019, we had 12 employees, of which 10 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 VAZALORE 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, our Chief Financial Officer, Rita O'Connor, and our Chief Medical Officer, Efthymios Deliargyris. If we are not able to retain Mr. Valentino, Ms. Giordano, Ms. O'Connor or Dr. Deliargyris, 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, Ms. O'Connor and Dr. Deliargyris, 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 Sparta, New Jersey, which in the past has experienced weather-related incidents.. 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 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.

Risks Related to Product Safety and Efficacy Issues

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

VAZALORE, 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 VAZALORE which may result in changes to the distribution program and additional restrictions on the use of VAZALORE 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 VAZALORE — 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 VAZALORE 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 VAZALORE is owned by UT. Our development and commercialization of VAZALORE is subject to our UT License Agreement. Under our UT License Agreement, 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 UT License Agreement, 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 VAZALORE 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 VAZALORE 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 VAZALORE 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 have received approval for the original NDA for VAZALORE 325 mg, neither we nor any future partner are permitted to market VAZALORE or any other product candidate in the United States until we receive regulatory approval from the FDA.

We have not submitted an application or obtained marketing approval for doses of VAZALORE 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 VAZALORE 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 VAZALORE 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 VAZALORE 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 VAZALORE, changes to these regulations could have a significant adverse effect on reimbursement rates and, indirectly, on sales of VAZALORE.

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 VAZALORE;
- 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 VAZALORE, 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, 2019, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially owned approximately 23.0% 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 currently have Series A Preferred Stock outstanding and our certificate of incorporation authorizes our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board also has the authority to issue preferred stock without further stockholder approval. We currently have 15,000 shares of Series A Preferred Stock outstanding, which is convertible at the holder's option at any time into shares of common stock with an initial conversion price of $2.60 per share, subject to certain adjustments. The Series A Preferred Stock Certificate of Designations provides for the payment of cash dividends on the Series A Preferred Stock at a rate of 8.00% per annum, provided that we may pay dividends in-kind through the issuance of additional shares to holders of the Series A Preferred Stock. Our Series A Preferred Stock gives its holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of common stock, among other things. In addition, our Board could authorize the issuance of additional series of preferred stock with such rights preferential to the rights of our common stock, including the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

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 common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, no dividends will be declared or paid or set apart for payment on our common stock unless all accumulated accrued and unpaid dividends in respect of our Series A Preferred Stock have been paid or declared and set apart for payment to the holders of Series A Preferred Stock. Our $15.0 million Term Loan Facility with SVB limits our ability to pay dividends, including to the holders of our Series A Preferred Stock, in certain circumstances. These limitations may cause us to be unable to pay dividends on the Series A Preferred Stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts 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 facility consists of office space in Sparta, New Jersey. In Sparta, we occupy approximately 2,463 and 2,232 square feet of office space, with rent of $5,542 and an average of $4,408 per month, respectively, under leases that expire September 30, 2021 and July 1, 2024, respectively. In addition, we lease 5,006 square feet of office space in New York, New York from the former Dipexium headquarters with rent of $19,146 per month under a lease that expires July 31, 2021. We currently sublease the New York facility, which generates income of $17,531 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.

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."

Stockholder Information

As of March 10, 2020, there were approximately 79 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. The Certificate of Designations for our Series A Preferred Stock prohibits the payment of dividends at any time that we are not current in the payment of dividends with respect to the Series A Preferred Stock. Our 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, 2019, 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	1,666,797	$ 13.96	598,650
Equity compensation plans not approved by stockholders	-	$ -	-
Total	1,666,797	$ 13.96	598,650

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

In December 2018, we entered into the Purchase Agreement with Park West Investors Master Fund, Limited, a Cayman Islands exempted company, and Park West Partners International, Limited, a Cayman Islands exempted company, for the Private Placement of $15.0 million of our Series A Preferred Stock, at a price of $1,000 per share, in reliance upon the exemption from securities registration afforded by the provisions of Regulation D under the Securities Act of 1933. Following the attainment of stockholder approval of the transaction at a special meeting of stockholders on February 19, 2019, the Private Placement closed on February 20, 2019. Pursuant to the Certificate of Designations of the Series A Preferred Stock, each share of Series A Preferred Stock can be converted, at the holder's option at any time, into shares of the Company's common stock at a conversion rate equal to the quotient of (i) the $1,000 stated value divided by (ii) the initial conversion price of $2.60, subject to specified adjustments for stock splits, cash or stock dividends, recapitalizations, combinations, subdivisions or other similar events as set forth in the Certificate of Designations. In connection with the Purchase Agreement, we also issued warrants to purchase an aggregate of 500,000 shares of our common stock to the investors, exercisable at a price of $3.50 per share, provided that the Private Placement did not close by April 15, 2019. Following the closing of the Private Placement, the investors surrendered the warrants to the Company for cancellation. In March 2019, the Company filed a registration statement on Form S-3 to register for resale the shares issuable upon conversion of the Series A Preferred Stock.

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 focused on developing our clinically-validated and patent-protected PLxGuard delivery system to provide more effective and safer products. Our PLxGuard delivery system works by targeting the release of active pharmaceutical ingredients to various portions of the GI tract. We believe this has the potential to improve the absorption of many drugs currently on the market or in development, and to reduce the risk of stomach erosions, ulcers and bleeding associated with aspirin and ibuprofen, and potentially other drugs.

The FDA approved our lead product, VAZALORE 325 mg, which is a novel formulation of aspirin using the PLxGuard delivery system intended to provide better antiplatelet effectiveness for vascular disease prevention and treatment as compared to the current standard of care, enteric-coated aspirin and significantly reduce gastric side effects as compared with immediate-release aspirin. VAZALORE 325 mg (formerly PL2200 Aspirin 325 mg and Aspertec 325 mg) was originally approved under the drug name aspirin, and the proprietary name 'VAZALORE' was granted subsequent to the FDA approval. A companion 81 mg dose of the same novel formulation,VAZALORE 81 mg, is in late-stage development and will be the subject of a sNDA, leveraging the already approved status of VAZALORE 325 mg. We are focused on collecting the data, including initiating a bioequivalence study, required for post-approval manufacturing changes which will be included in the sNDA filing for VAZALORE 325 mg and to support approval of low dose VAZALORE 81 mg. The Company will be able to better assess the timing of its product launch once the sNDA filings has been submitted.

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 VAZALORE 325 mg and anticipated approval for VAZALORE 81 mg for OTC and prescription use when recommended by physicians for vascular disease treatment and prevention. Given our clinical demonstration of better antiplatelet efficacy (as compared with enteric-coated aspirin) and better GI tolerability, we intend to market VAZALORE to the healthcare professional and the consumer through several marketing channels, including a physician-directed sales force. 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 generally accepted accounting principles 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 the financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

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

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

Use of Estimates

The preparation of 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 liability the fair value of stock-based compensation, allowance for inventory obsolescence, allowance for doubtful accounts, contingent liabilities, fair value and depreciable lives of long-lived assets, and deferred taxes and associated valuation allowance. Actual results could differ from those estimates.

Fair Value Measurements

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

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

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

The Company's financial instruments (cash and cash equivalents, receivables, accounts payable and accrued liabilities) are carried in the consolidated balance sheet at cost, which reasonably approximates fair value based on their short-term nature. The Company's warrant liability is 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 term loan approximates its face value of $4,375,000 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, manufacturing activities, and include fees paid to various entities that perform research related services for the Company.

Stock-Based Compensation

The Company recognizes expense in the consolidated statements of operations for the fair value of all stock-based compensation to key employees, nonemployee directors and advisors, 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 accounts for forfeitures as they occur.

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 $0.6 million and $0.8 million for the years ended December 31, 2019 and 2018, respectively. All the revenue recognized in 2019 and 2018 is attributable to work performed under an award of a National Institutes of Health grant. This grant is nearing completion.

Operating Expenses

Total operating expenses were $14.8 million during the year ended December 31, 2019, a 26% increase from operating expenses of $11.7 million during the year ended December 31, 2018. Operating expenses for the years ended December 31, 2019 and 2018 were as follows:

	Years Ended December 31,		Increase (Decrease)	
	2019	2018	$	%
Operating Expenses				
Research and development expenses	$ 4,741,130	$ 3,922,665	$ 818,465	20.9%
General and administrative expenses	10,026,627	7,791,600	2,235,027	28.7%
Total operating expenses	$ 14,767,757	$ 11,714,265	$ 3,053,492	26.1%

Research and Development Expenses

Research and development expenses totaled $4.7 million in the year ended December 31, 2019, compared to $3.9 million in the prior year, reflecting continued product development and manufacturing activities for VAZALORE. This increase was due to the manufacture, packaging, stability and analytical costs related to the registration batches, which provide data to be submitted in the Company's sNDA filings.

General and Administrative Expenses

General and administrative expenses totaled $10.0 million in the year ended December 31, 2019, compared to $7.8 million in the prior year. This increase is due to commercial-related activities to support the upcoming launch of $1.9 million and payments associated with the UT License Agreement of $0.3 million.

Other income (expense), net

Other income (expense), net totaled $6.3 million of net other expense for the year ended December 31, 2019, compared to $11.9 million of net income in the prior year. The change is primarily attributable to the non-cash change in fair value of warrant liability primarily due to the fluctuation of the price of the Company's common stock ($5.7 million of other expense for the year ended December 31, 2019, as compared to $12.7 million of other income in the prior year).

Liquidity and Capital Resources

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

	Years Ended December 31,	
	2019	2018
Net cash used in operating activities	$ (12,659,035)	$ (9,499,231)
Net cash used in investing activities	$ (230,294)	$ (654,870)
Net cash provided by financing activities	$ 12,640,366	$ -

Net Cash Used in Operating Activities

Net cash used in operating activities of $12.7 million for the year ended December 31, 2019 primarily reflects our net loss for the period of $20.5 million adjusted for various non-cash charges and income, including (i) $5.7 million change in fair value of warrant liability reflected as other expense, (ii) net operating asset/liability changes of $0.9 million, (iii) $0.9 million of stock-based compensation, (iv) depreciation and amortization expense of $0.2 million and (v) $0.2 million of non-cash interest expense.

Net cash used in operating activities of $9.5 million for the year ended December 31, 2018 primarily reflects our net income for the period of $0.9 million adjusted for various non-cash charges and income, including (i) $12.7 million change in fair value of warrant liability reflected as other income, partially offset by (ii) net operating asset/liability changes of $0.3 million, (iii) $0.8 million of stock-based compensation, (iv) an increase in the provision for obsolete inventory of $0.8 million, (v) depreciation and amortization expense of $0.2 million and (vii) $0.2 million of non-cash interest expense.

Net Cash Used in Investing Activities

Net cash used in investing activities totaled $0.2 million in net uses in the year ended December 31, 2019 and primarily reflects $0.2 million of capital expenditures for equipment purchases, net of $11,000 of proceeds from the sale of equipment.

Net cash used in investing activities totaled $0.7 million in net uses in the year ended December 31, 2018 and reflects capital expenditures for equipment purchases of $0.5 million and leasehold improvements of $0.2 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $12.6 million in the year ended December 31, 2019, consisting of proceeds from the issuance of our common and preferred stock, offset by repayment of a portion of our long-term debt. We had no cash flows from financing activities in 2018.

Future Liquidity and Capital Needs

As of December 31, 2019, we had working capital of $8.2 million and cash and cash equivalents of $14.0 million. In March 2019, we entered into the Equity Distribution Agreement with JMP to issue and sell shares of our common stock, having an aggregate offering price of up to $12.5 million, from time to time during the term of the Equity Distribution Agreement, through an “at-the-market” equity offering program at our sole discretion, under which JMP will act as our agent. As of December 31, 2019, we had sold approximately $2.3 million of shares of our common stock pursuant to the Equity Distribution Agreement, and received proceeds of $2.1 million, net of commissions and fees. In addition, in March 2020 we entered into a purchase agreement with certain investors, including funds affiliated with Park West Asset Management LLC and an affiliate of MSD Partners, L.P., pursuant to which the Company has agreed to issue 8,000 shares of Series B Convertible Preferred Stock for gross proceeds of $8.0 million (the "Series B Private Placement"). The closing of the Series B Private Placement is contingent on the Company obtaining stockholder approval. Based on the Company’s expected operating cash requirements, we believe our cash on-hand at December 31, 2019, in addition to the $8.0 million gross proceeds from the Series B Private Placement, is adequate to fund operations for at least twelve months from the date that these financial statements were issued.

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, 2019, we had an accumulated deficit of $86.9 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 VAZALORE 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, in addition to the proceeds from the Private Placement, the “at-the-market” program and the Series B Private Placement 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.

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 our 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 did not have any off-balance sheet arrangements as of December 31, 2019 or 2018.

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, 2019, 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, 2019, using the criteria set forth by COSO in Internal Control — Integrated Framework (2013), our management has concluded that, as of December 31, 2019, 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, 2019 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, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this Item will be set forth in our definitive proxy statement for our 2020 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 2020 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 2020 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 2020 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 2020 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 AND 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, 2019 and 2018, the related consolidated statements of operations, changes in series A convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years ended December 31, 2019 and 2018, the footnotes thereto, and the reports of Marcum LLP, independent registered public accounting firms, are set forth on pages F-1 through F-21 of this Form 10-K.

(b) Exhibits:

See Exhibit Index of this Form 10-K for a description of the exhibits filed as part of, or incorporated by reference in, this Form 10-K.

(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.

ITEM 16. FORM 10-K SUMMARY.

None.

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 Series A Convertible Preferred Stock and 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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PLx Pharma Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, changes in series A convertible preferred stock and stockholders' equity (deficit), and cash flows for 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, 2019 and 2018, and the results of its operations and its cash flows for 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/ Marcum LLP

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

Marcum LLP
Houston, Texas
March 13, 2020

PLx Pharma Inc.
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 14,001,304	$ 14,250,267
Accounts receivable	18,683	18,234
Prepaid expenses and other current assets	263,268	421,933
Deferred financing costs	-	174,976
TOTAL CURRENT ASSETS	14,283,255	14,865,410
NON-CURRENT ASSETS		
Property and equipment, net	1,466,646	1,394,230
Right of use assets	618,158	-
Goodwill	2,061,022	2,061,022
Security deposit	73,665	67,714
TOTAL ASSETS	$ 18,502,746	$ 18,388,376
LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 928,921	$ 687,257
Accrued bonuses	1,166,821	1,048,393
Accrued interest	34,964	60,366
Current portion of term loan, net of discount and fees	3,658,121	2,909,709
Other current liabilities	304,603	26,935
TOTAL CURRENT LIABILITIES	6,093,430	4,732,660
NON-CURRENT LIABILITIES		
Accrued interest, net of current portion	501,826	309,440
Term loan, net of discount, fees and current portion	622,265	4,280,385
Warrant liability	8,247,679	2,537,317
Accrued dividends	1,058,498	-
Other liabilities	409,431	84,281
TOTAL LIABILITIES	16,933,129	11,944,083
Commitments and contingencies		
Series A convertible preferred stock: $0.001 par value; liquidation value of $15,000,000; 45,000 shares designated, 15,000 and 0 shares issued and outstanding	13,661,578	-
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock; $0.001 par value; 955,000 shares authorized; none issued and outstanding	-	-
Common stock; $0.001 par value; 100,000,000 shares authorized; 9,156,260 and 8,743,950 shares issued and outstanding	9,156	8,744
Additional paid-in capital	74,837,046	72,871,317
Accumulated deficit	(86,938,163)	(66,435,768)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(12,091,961)	6,444,293
TOTAL LIABILITIES, SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 18,502,746	$ 18,388,376

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31, 2019	2018
REVENUES:		
Federal grant	$ 565,464	$ 753,108
TOTAL REVENUES	565,464	753,108
OPERATING EXPENSES:		
Research and development	4,741,130	3,922,665
General and administrative	10,026,627	7,791,600
TOTAL OPERATING EXPENSES	14,767,757	11,714,265
OPERATING LOSS	(14,202,293)	(10,961,157)
OTHER INCOME (EXPENSE):		
Interest income	405,239	297,800
Interest and other expense	(994,979)	(1,145,761)
Change in fair value of warrant liability	(5,710,362)	12,705,598
TOTAL OTHER INCOME (EXPENSE)	(6,300,102)	11,857,637
INCOME (LOSS) BEFORE INCOME TAXES	(20,502,395)	896,480
Income taxes	-	-
NET INCOME (LOSS)	$ (20,502,395)	$ 896,480
Preferred dividends and beneficial conversion feature	(13,750,806)	-
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (34,253,201)	$ 896,480
Net income (loss) per common share - basic	$ (3.84)	$ 0.10
Net income (loss) per common share - diluted	$ (3.84)	$ 0.10
Weighted average shares of common shares - basic	8,916,190	8,733,220
Weighted average shares of common shares - diluted	8,916,190	8,733,220

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF CHANGES IN SERIES A CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

	Temporary Equity		Permanent Equity				
	Series A Convertible Preferred Stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2017	-	$ -	8,722,823	$ 8,723	$ 71,939,917	$ (67,332,248)	$ 4,616,392
Stock-based compensation expense					841,421		841,421
Common shares issued to vendor			21,127	21	89,979		90,000
Net income						896,480	896,480
Balance at December 31, 2018	-	$ -	8,743,950	$ 8,744	$ 72,871,317	$ (66,435,768)	$ 6,444,293
Stock-based compensation expense					875,851		875,851
Issuance of Series A Preferred Stock, net of issuance costs	15,000	13,661,578					-
Series A Preferred - beneficial conversion feature at issuance					12,692,308		12,692,308
Series A Preferred - conversion feature deemed dividend					(12,692,308)		(12,692,308)
Common shares issued to vendor			13,601	13	44,987		45,000
Common shares issued, net of issuance costs			398,709	399	2,103,389		2,103,788
Series A Preferred - declared dividends					(1,058,498)		(1,058,498)
Net loss						(20,502,395)	(20,502,395)
Balance at December 31, 2019	15,000	$13,661,578	9,156,260	$ 9,156	$ 74,837,046	$ (86,938,163)	$ (12,091,961)

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ (20,502,395)	$ 896,480
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	158,253	200,957
Stock-based compensation	875,851	841,421
Amortization of debt discounts and issuance costs	215,292	247,943
Change in fair value of warrant liability	5,710,362	(12,705,598)
Provision for obsolete inventory	-	770,619
Loss on sale of property and equipment	12,398	-
Changes in operating assets and liabilities		
Accounts receivable	(449)	1,150
Inventory	-	(524,245)
Prepaid expenses and other current assets	152,714	(109,200)
Vendor deposit	-	707,103
Right of use assets	94,376	-
Accounts payable and accrued liabilities	448,867	(194,524)
Accrued bonuses	118,428	198,690
Accrued interest	166,984	225,870
Other current and long-term liabilities	(109,716)	(55,897)
Net cash used in operating activities	(12,659,035)	(9,499,231)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(241,736)	(654,870)
Proceeds from sale of property and equipment	11,442	-
Net cash used in investing activities	(230,294)	(654,870)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of Series A convertible preferred stock	13,661,578	-
Net proceeds from issuance of common stock	2,103,788	-
Repayments of long-term debt	(3,125,000)	-
Net cash provided by financing activities	12,640,366	-
NET DECREASE IN CASH AND CASH EQUIVALENTS	(248,963)	(10,154,101)
Cash and cash equivalents, beginning of year	14,250,267	24,404,368
Cash and cash equivalents, end of year	$ 14,001,304	$ 14,250,267
SUPPLEMENTAL INFORMATION		
Cash paid during the period for:		
Income taxes	$ -	$ -
Interest	$ 600,303	$ 671,146
NON-CASH INVESTING AND FINANCING TRANSACTIONS		
Property and equipment included in accounts payable	$ 12,773	$ -
Deferred financing costs included in accounts payable	$ -	$ 174,976
Preferred stock beneficial conversion feature and dividends	$ 13,750,806	$ -
Value of common shares issued to vendor for services	$ 45,000	$ 90,000

See accompanying notes to consolidated financial statements.

PLx Pharma Inc.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019

NOTE 1. BACKGROUND AND ORGANIZATION

Business Operations

PLx Pharma Inc. (the “Company”, "we," "our" or "us"), together with its subsidiaries PLx Opco Inc. and PLx Chile SpA, is a late stage startup specialty pharmaceutical company focusing initially on commercializing two patent-protected lead products: VAZALORE™ 325 mg and VAZALORE™ 81 mg (referred to together as “VAZALORE”). VAZALORE 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. The Company dissolved its wholly-owned and dormant subsidiary Dipexium Pharmaceuticals Ireland Limited in December 2018.

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”). In December 2013, PLx Texas converted from a Texas corporation to a Texas limited liability company and changed its name to PLx Pharma LLC ("PLx LLC"). In July 2015, PLx LLC reincorporated into a Delaware corporation, renamed PLx Pharma Inc. ("Old PLx"), effective July 27, 2015.

In December 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. 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.

NOTE 2. LIQUIDITY AND GOING CONCERN

The accompanying consolidated financial statements have been prepared assuming that the Company 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 its obligations as they become due. The Company has not generated any revenue from sale of products, and has incurred operating losses in each year since it commenced operations. As of December 31, 2019, the Company had an accumulated deficit of $86.9 million. The Company expects to continue to incur significant expenses and increasing operating losses for the foreseeable future as the Company continues the development and commercialization of its candidates. However, based on the Company’s expected operating cash requirements, it believes its cash on-hand at December 31, 2019, in addition to the gross proceeds from the sale of Series B Convertible Preferred Stock to certain investors pursuant to a March 2020 purchase agreement 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 subsidiary, PLx Opco Inc. All significant intercompany balances and transactions have been eliminated within the 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, the fair value of warrant liability, the fair value of stock-based compensation, allowance for inventory obsolescence, allowance for doubtful accounts, contingent liabilities, fair value and depreciable lives of long-lived assets, and deferred taxes and associated valuation allowance. Actual results could differ from those estimates.

Foreign Currency

The functional currency of our international subsidiary 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 an original 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, 2019, the Company had cash and cash equivalents of $14.0 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, 2019 and 2018, respectively.

Inventory

Inventory is stated at the lower of cost or net realizable value, using the average cost method. Inventory as of December 31, 2019 and 2018 was comprised of raw materials for the manufacture of VAZALORE. The Company regularly reviews inventory quantities on hand and assesses the need for an allowance for obsolescence. The allowance for obsolete inventory was $0.5 million and $1.0 million as of December 31, 2019 and 2018, respectively, resulting in net inventory of zero for both periods.

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 term loan approximates its face value of $4,375,000 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 8.

Property and Equipment

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

Leases

As described further below in this Note 3, the Company adopted new accounting guidance for leases effective January 1, 2019. Subsequent to the adoption at the inception of a contract, the Company determines if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases. Operating lease ROU assets are included in leased assets and operating lease liabilities are included in other current and non-current liabilities in the Company's consolidated balance sheets. As of December 31, 2019, the Company did not have any finance leases.

Goodwill

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.

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 the Company's consolidated statements of operations.

The Company has not identified any events or changes in circumstances that indicate that a potential impairment of goodwill occurred during the years ended December 31, 2019 or 2018.

Revenue Recognition

As described further below in this Note 3, on January 1, 2018, the Company adopted Topic 606, Revenue from Contracts with Customer using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018.

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers; (ii) identification of distinct performance obligations in the contract; (iii) determination of contract transaction price; (iv) allocation of contract transaction price to the performance obligations; and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation. The Company recognizes revenues upon the satisfaction of its performance obligations (upon transfer of control of promised goods or services to customers) in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services. Deferred revenue results from cash receipts from or amounts billed to customers in advance of the transfer of control of the promised services to the customer and is recognized as performance obligations are satisfied. When sales commissions or other costs to obtain contracts with customers are considered incremental and recoverable, those costs are deferred and then amortized as selling and marketing expenses on a straight-line basis over an estimated period of benefit.

The Company's current sole revenue arrangement is a cost-reimbursable federal grant with the National Institutes of Health. The Company recognizes revenue on this grant as grant-related expenses are incurred by the Company or its subcontractors. The Company recognized $0.6 million and $0.8 million of revenue under this arrangement during the years ended December 31, 2019 and 2018, respectively. This grant will be completed in early 2020.

The Company has not incurred incremental costs to obtain contracts with customers or material costs to fulfill contracts with customers and did not have any material contract assets or liabilities as of December 31, 2019 and December 31, 2018.

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, manufacturing activities, and include fees paid to various entities that perform research related services for the Company.

Stock-Based Compensation

The Company recognizes expense in the consolidated statements of operations for the fair value of all stock-based compensation to key employees, nonemployee directors and advisors, 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 accounts for forfeitures as they occur.

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. 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 currently has tax returns open for examination by the applicable taxing authority for all years since 2015.

Income (Loss) Per Share

In periods of net loss, 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. The Series A convertible preferred stock (the "Series A Preferred Stock") contains non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic earnings per share excludes from the numerator net income attributable to the Series A Preferred Stock and excludes the impact of those shares from the denominator.

In 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. In periods of net income, diluted earnings per share is computed using the more dilutive of the "two class method" or the "treasury method." Dilutive earnings per share under the "two class method" is calculated by dividing net income available to common stockholders as adjusted for the participating impacts of the Series A Preferred Stock, by the weighted-average number of shares outstanding plus the dilutive impact of all other potential dilutive common shares, consisting primarily of common shares underlying common stock options and stock purchase warrants using the treasury stock method. Dilutive earnings per share under the "treasury method" is calculated by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the dilutive 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 preferred stock using the if-converted method.

None of the potential dilutive securities had a dilutive impact during the years ended December 31, 2019 and 2018.

The number of anti-dilutive share for the years ended December 31, 2019 and 2018 consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, and (iii) convertible preferred stock which have been excluded from the computation of diluted income per share, was 10,547,735 and 3,911,302 shares, respectively.

Recent Accounting Developments

Recently Adopted Guidance

In May 2014, the Financial Accounting Standards Board (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 adopted this guidance effective January 1, 2018 on a modified retrospective basis and it did not have any impact 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 Company adopted this guidance effective January 1, 2018 on a retrospective basis and it did not have a material impact on the 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. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company adopted this guidance effective January 1, 2019 using the following practical expedients:

- the Company did not reassess if any expired or existing contracts are or contain leases; and
- the Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combines lease and non-lease elements of its operating leases.

Upon adoption of the new guidance on January 1, 2019, the Company recorded a ROU of $712,534 and recognized a lease liability of $789,543, with no resulting cumulative effect adjustment to retained earnings.

In June 2018, the FASB issued guidance with respect to the accounting for nonemployee share-based payment awards. The guidance generally aligns the accounting for nonemployee awards to that for employees. The guidance is effective for fiscal years beginning after December 15, 2018. The Company adopted this guidance on January 1, 2019 and the adoption did not have a material impact on its financial statements.

Unadopted Guidance

In August 2018, the FASB issued guidance with respect to the disclosure requirements for fair value measurements. The guidance intends to improve the effectiveness of the disclosures relating to recurring and nonrecurring fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019. Portions of the guidance are to be adopted prospectively while other portions are to be adopted retroactively. Early adoption is permitted. 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 standards, or standards issued but not yet effective, if adopted, would have a material effect on the accompanying consolidated financial statements.

Reclassifications

Certain reclassifications have been made to the prior-year financial statements to conform to the current-year presentation. These reclassifications had no effect on the reported results of operations.

Subsequent Events

The Company’s management reviewed all material events through the date the consolidated financial statements were issued for subsequent event disclosure consideration.

NOTE 4. LONG-LIVED ASSETS

Property and Equipment

Property and equipment at December 31, 2019 and 2018 consisted of the following:

Asset Descriptions	Useful Lives (years)	December 31, 2019	December 31, 2018
Computer equipment	4	$ 41,839	$ 41,839
Lab equipment	5	17,019	17,019
Office equipment, furniture and fixtures	5	106,486	106,486
Leasehold improvements	lease term	184,989	175,736
Manufacturing equipment	7	1,559,195	1,345,230
Subtotal		1,909,528	1,686,310
Less: Accumulated depreciation and amortization		(442,882)	(292,080)
Total property and equipment, net		$ 1,466,646	$ 1,394,230

Depreciation and amortization expense for the years ended December 31, 2019 and 2018 was $158,253 and $200,957, respectively. During the year ended December 31, 2019, the Company sold equipment for proceeds of $11,442 and recognized a loss of $12,398.

Goodwill

The Company established goodwill in 2017 in connection with the Merger. The Company's goodwill at December 31, 2019 and 2018 was $2.1 million. The Company has not identified any events or changes in circumstances that indicate that a potential impairment of goodwill occurred during the years ended December 31, 2019 or 2018. As such, the Company believes goodwill is not impaired.

NOTE 5. 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. The Company had the right to borrow an additional $7.5 million on or before December 31, 2018; this right expired unexercised.

The Term Loan Facility carries interest at a floating rate of 4.0% above the prime rate per annum (for a total interest rate of 8.8% at December 31, 2019), with interest payable monthly. The monthly payments will consist of interest-only for the first 18 months, after which the Term Loan 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 9, 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 original principal amount. 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, which was recorded as debt discount of $304,201 on the date of issuance.

At December 31, 2019 and 2018, $4.4 million and $7.5 million, respectively, of face value of the Term Loan was presented in the accompanying consolidated balance sheets net of current unamortized discounts and issuance costs of $91,879 and $215,291, and long-term unamortized discounts and issuance costs of $2,735 and $94,615, respectively.

Total interest expense recognized for the years ended December 31, 2019 and 2018 was $1.0 million and $1.1 million, respectively.

NOTE 6. STOCKHOLDERS' EQUITY

Common Stock

Equity Distribution Agreement

In March 2019, the Company entered into an equity distribution agreement with JMP Securities, Inc. ("JMP"). Pursuant to the terms of the agreement, the Company may sell from time to time, at its option, shares of the Company's common stock, through JMP, as sales agent, with an aggregate sales price of up to $12.5 million. Any sales of shares pursuant to the agreement will be made under the Company's effective "shelf" registration statement, which allows it to sell debt or equity securities in one or more offerings up to a total public offering price of $75 million. In 2019, the Company issued 398,709 shares under the agreement generating gross proceeds of $2.3 million and net proceeds of $2.1 million after deducting legal and commission costs. As of December 31, 2019, approximately $10.2 million remained available under the agreement.

Convertible Series A Preferred Stock

In December 2018, the Company entered into a purchase agreement with certain accredited investors for the private placement of $15.0 million of Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") pending stockholders' approval, which approval was subsequently obtained on February 19, 2019. Accordingly, the Company completed the private placement on February 20, 2019, raising $15.0 million through the issuance of 15,000 shares of Series A Preferred Stock. The Series A Preferred Stock was issued at $1,000 per share and is convertible into common shares at a conversion price of $2.60 per share, subject to certain adjustments. Holders of the Series A Preferred Stock will be entitled to an initial dividend rate of 8.0% per annum, which will stop accruing on the date of the FDA's approval of the supplemental sNDA of VAZALORE 325 mg and VAZALORE 81mg. The dividends are compounded quarterly and payable in cash or shares of Series A Preferred Stock at the Company's option. The Series A Preferred Stock carries a liquidation preference equal to its stated value of $1,000 plus accrued and unpaid dividends.

The Series A Preferred Stock is classified as temporary equity due to the presence of certain contingent cash redemption features. As a result of the excess value of the Company's common stock on the issuance date over the conversion price of the Series A Preferred Stock, a beneficial conversion feature in the amount of $12.7 million was bifurcated from the host instrument and accounted for separately as an increase in additional paid-in capital in equity, and resulted in a deemed dividend during the year ended December 31, 2019 of $12.7 million which was accounted for as a decrease in additional paid-in capital in equity due to the Company's accumulated deficit position. At December 31, 2019, the carrying value of the temporary equity was $13.7 million, net of $1.3 million in offering costs.

The Company recognized $1.1 million (or $70.57 per share of Series A Preferred Stock) of total dividends on the Series A Preferred Stock during the year ended December 31, 2019. No dividends were recognized on common stock during any of the periods presented.

Warrants

In connection with a June 2017 equity transaction, the Company issued stock purchase warrants to purchase 2,646,091 shares of common stock at an exercise price of $7.50 per share. The warrants, exercisable beginning six months and one day after issuance, have a 10-year term and are liability classified due the holders' right to require the Company to repurchase the warrants for cash upon certain deferred fundamental transactions. See Note 8 for the fair value measurement of the warrant liability.

In connection with entry into the Term Loan Facility, the Company issued to SVB and one of its affiliates, warrants to purchase an aggregate of 58,502 shares of the Company's common stock at an exercise price of $6.41 per share (see Note 5). These warrants are immediately exercisable, have a 10-year term, contain a cashless exercise provision, and are classified in equity.

Stock Options

Following is a summary of option activities for the years ended December 31, 2019 and 2018:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2017	1,166,709	$ 18.54	7.84	$ 90,097
Granted	85,000	$ 3.46		
Cancelled	(45,000)	$ 6.55		
Outstanding, December 31, 2018	1,206,709	$ 17.93	6.97	$ -
Granted	714,350	$ 5.76		
Cancelled	(254,262)	$ 9.78		
Outstanding, December 31, 2019	1,666,797	$ 13.96	7.22	$ 91,475
Exercisable, December 31, 2019	928,780	$ 20.59	5.73	$ 30,491

On September 13, 2018, the Company's stockholders approved the 2018 Incentive Plan (the "2018 Plan"). The 2018 Plan provides that the Company may grant equity interests to employees, consultants and members of the Board of Directors in the form of incentive and nonqualified stock options, restricted stock and restricted stock units, stock appreciation rights and various other forms of stock-based awards. There are 1,250,000 shares authorized to be issued pursuant to the 2018 Plan. As of December 31, 2019, 598,650 shares are available for issuance under the 2018 Plan.

Prior to the approval of the 2018 Plan, the Company granted options to employees, directors, advisors, and consultants from two former plans – the Old PLx Omnibus Stock Option Plan and the Dipexium 2013 Equity Incentive Plan (the "Prior Plans"). Upon the adoption of the 2018 Plan, the Prior Plans were frozen, and no new awards can be issued pursuant to the Prior Plans. The Company is no longer authorized to grant awards under these two plans.

The Company granted 714,350 options during the year ended December 31, 2019 with an aggregate fair value of $2.9 million calculated using the Black-Scholes model on the grant date. Variables used in the Black-Scholes model include: (1) discount rate range from 1.9% to 2.5%, (2) expected life of 6.0 years, (3) expected volatility of 82%, and (4) zero expected dividends.

The Company granted 85,000 options during the year ended December 31, 2018 with an aggregate fair value of $207,537 calculated using the Black-Scholes model on the grant date. Variables used in the Black-Scholes model include: (1) discount rate of 2.6% to 2.8%, (2) expected life of 6.0 years, (3) expected volatility of 76% to 82%, and (4) zero expected dividends.

As of December 31, 2019, the Company had $2.2 million in unamortized expense related to unvested options which is expected to be expensed over a weighted average of 2.1 years.

During the years ended December 31, 2019 and 2018, the Company recorded $875,851 and $841,421, respectively, in total compensation expense related to the stock options. For the year ended December 31, 2019, $872,244 of stock-based compensation expense was classified as general and administrative expenses and $3,607 was classified as research and development expenses in the accompanying consolidated statement of operations. For the year ended December 31, 2018, $827,466 of stock-based compensation expense was classified as general and administrative expenses and $13,955 was classified as research and development expenses in the accompanying consolidated statement of operations.

NOTE 7. COMMITMENTS AND CONTINGENCIES

Lease Agreements

The Company presently leases office space under operating lease agreements expiring on July 31, 2021, October 3, 2021, and June 30, 2024. The office leases require the Company to pay for its portion of taxes, maintenance and insurance. Rental expense under these agreements was $395,190 and $114,460 for the years ended December 31, 2019 and 2018, respectively. Rent expense for 2018 excludes New York lease costs as it was not restated for the new lease guidance.

All the Company's existing leases as of December 31, 2019 are classified as operating leases. As of December 31, 2019, the Company has five operating leases for facilities and office equipment with remaining terms expiring from 2019 through 2024 and a weighted average remaining lease term of 2.5 years. Many of the Company's existing leases have fair value renewal options, none of which the Company considers certain of being exercised or included in the minimum lease term. Weighted-average discount rates used in the calculation of the Company's lease liability are approximately 9.5%. In addition, the Company is the lessor for office space in New York that it sublets to a tenant; the sublease expires in 2021.

Lease costs, net of sublease income, for the year ended December 31, 2019 consisted of the following:

Operating lease cost	$	374,667
Variable lease costs		20,523
Sublease income		(234,098)
Total lease costs	$	161,092

A maturity analysis of the Company's operating leases follows:

Future undiscounted cash flows:

2020	$	356,196
2021		262,850
2022		60,819
2023		60,264
2024		30,132
Total		770,261
Discount factor		(90,435)
Total lease liability		679,826
Current lease liability		(304,603)
Non-current lease liability	$	375,223

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 (the "University"), 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 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. The Company recognized total expenses of $392,840 and $85,330 related to the University in the years ended December 31, 2019 and 2018, respectively.

Investor Relations Agreement

On March 21, 2017, the Company entered into an agreement with an investor relations firm which expired in June 2019. The Company agreed to pay 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 shares of the Company's common stock. The Company issued 13,601 and 21,127 shares of common stock during the years ended December 31, 2019 and 2018, respectively, as full payment for services during such period.

NOTE 8. FAIR VALUE MEASUREMENTS

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

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

- Level 1: Quoted prices in active markets for identical assets or liabilities that the organization has the ability to access at the reporting date.
- Level 2: Inputs other than quoted prices included in Level 1, which are either observable or that can be derived from or corroborated by observable data as of the reporting date.
- Level 3: Inputs include those that are significant to the fair value of the asset or liability and are generally less observable from objective resources and reflect the reporting entity's 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 years ended December 31, 2019 and 2018:

Description	Balance at December 31, 2017	Established in 2018	Change in Fair Value	Balance at December 31, 2018
Warrant liability	$ 15,242,915	$ -	$ (12,705,598)	$ 2,537,317

Description	Balance at December 31, 2018	Established in 2019	Change in Fair Value	Balance at December 31, 2019
Warrant liability	$ 2,537,317	$ -	$ 5,710,362	$ 8,247,679

The following table identifies the carrying amounts of such liabilities at December 31, 2019 and 2018:

	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 2,537,317	$ 2,537,317
Balance at December 31, 2018	$ -	$ -	$ 2,537,317	$ 2,537,317

	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 8,247,679	$ 8,247,679
Balance at December 31, 2019	$ -	$ -	$ 8,247,679	$ 8,247,679

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 goodwill, at fair value on a non-recurring basis when they are deemed to be impaired. No such impairment was recognized in the years ended December 31, 2019 and 2018.

NOTE 9. INCOME TAXES

Income tax (expense) benefit for the years ended December 31, 2019 and 2018 consisted of the following:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Current:		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Deferred:		
Federal	7,432,665	1,446,640
State	1,459,313	244,896
Foreign	-	-
Change in valuation allowance	(8,891,978)	(1,691,536)
Total Benefit for Income Taxes	$ -	$ -

Significant components of the Company's deferred tax assets and liabilities consisted of the following at December 31, 2019 and 2018:

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Stock-based compensation	$ 4,514,806	$ 3,768,282
Tax credit carryforwards	1,966,817	1,790,387
Net operating loss carryforwards	19,381,496	11,745,648
Intangible assets	564,880	451,556
Other	637,687	373,314
Total deferred tax assets	27,065,686	18,129,187
Deferred tax liabilities:		
Property and equipment	331,231	305,619
Total deferred tax liabilities	331,231	305,619
Net deferred tax assets	26,734,455	17,823,568
Less valuation allowance	(26,734,455)	(17,823,568)
Total deferred tax assets (liabilities)	$ -	$ -

In connection with the adoption of ASC 842 (see Note 3), the Company recorded, outside of the tax provision, deferred tax assets and deferred tax liabilities of $174,963 and $193,872, respectively, and reduced its valuation allowance by $18,909.

The following table reconciles the U.S. federal statutory income tax rate in effect for 2019 and 2018 and the Company's effective tax rate:

	Year Ended December 31, 2019	Year Ended December 31, 2018
U.S. federal statutory income tax expense (benefit)	21.0%	21.0%
State and local income tax, net of benefits	6.8%	3.6%
Change in fair value of derivatives	(7.8%)	(348.0%)
Release of valuation allowance in connection with merger	-	-
Change in tax rates	-	-
True-up and other	23.3%	134.7%
Change in valuation allowance for deferred income tax assets	(43.3%)	188.7%
Effective income tax rate	0.0%	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 $5.9 million. The Company had net operating loss carry-forwards of $84.7 million as of December 31, 2019, 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.

Utilization of NOL and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code (the "Code" and "IRC"), as amended, as well as similar state provisions. In general, an ownership change as defined by the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding common stock of a company by certain stockholders or public groups. The Company experienced an ownership change within the meaning of IRC Section 382 during the year ended December 31, 2017. As a result, certain limitations apply to the annual amount of net operating losses that can be used to offset post ownership change taxable income.

As of December 31, 2019, the tax returns for the years from 2015 through 2018 remain open to examination by the Internal Revenue Service and various state authorities. ASC 740, "Income Taxes" requires that a valuation allowance is established when it is more likely than not that all, or a portion of, deferred tax assets will not be recognized. A review of all available positive and negative evidence needs to be considered, including the Section 382 limitation, the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. After consideration of all the information available, management believes that uncertainty exists with respect to the future realization of its deferred tax assets and has, therefore, established a full valuation allowance as of December 31, 2019, and 2018. For the year ended December 31, 2019, the change in valuation allowance was $8.9 million.

As of December 31, 2019, and 2018, the Company has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements. The Company's policy is to classify assessments, if any, for tax-related interest as income tax expenses. No interest or penalties were recorded during the years ended December 31, 2019 and 2018. The Company does not expect its unrecognized tax benefit position to change during the next twelve months.

NOTE 10. SUBSEQUENT EVENT

In March 2020, the Company entered into a purchase agreement with certain investors, including funds affiliated with Park West Asset Management LLC and an affiliate of MSD Partners, L.P., pursuant to which the Company has agreed to issue 8,000 shares of Series B Convertible Preferred Stock for gross proceeds of $8.0 million (the "Series B Private Placement"). Subject to approval of the Company's stockholders and the satisfaction of customary closing conditions, the transaction is expected to close in the second quarter of 2020.

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	Certificate of Amendment to the Amended Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 20, 2019 (File No. 001-36351)).
3.3	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)).
4.3	Amended and Restated Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed on February 20, 2019 (File No. 001-36351)).
4.4	Description of Registered Securities.*
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)).
10.14	PLx Pharma Inc. 2018 Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2018 (File No. 001-36351)).
10.15	Employment Agreement of Efthymios Deliargyris, dated as of August 29, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 31, 2018 (File No. 001-36351)).
10.16	Purchase Agreement, dated December 20, 2018, by and among the Company and the Investors set forth on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 21, 2018 (File No. 001-36351)).
10.17	Registration Rights Agreement, dated December 20, 2018, by and among the Company and the Investors set forth on the signature pages thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 21, 2018 (File No. 001-36351)).
10.18	Amendment to Employment Agreement with Natasha Giordano, dated March 7, 2019 (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed on March 8, 2019 (File No. 001-36351)).
10.19	Amendment to Employment Agreement with Rita O'Connor, dated March 7, 2019 (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed on March 8, 2019 (File No. 001-36351)).
10.20	Amendment to Employment Agreement with Rita O'Connor, dated March 16, 2018 (incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed on March 8, 2019 (File No. 001-36351)).
10.21	Amendment to Employment Agreement with Efthymios Deliargyris, dated March 7, 2019 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on March 8, 2019 (File No. 001-36351)).
10.22	Amendment to Employment Agreement with Michael Valentino, dated March 7, 2019 (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on March 8, 2019 (File No. 001-36351)).
10.23	Equity Distribution Agreement, dated March 25, 2019, by and between the Company and JMP Securities LLC (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 filed on March 25, 2019 (File No. 333-230478)).
10.24	Manufacturing Services Agreement, dated June 28, 2019, between the Company and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2019 (File No. 001-36351)).+
16.1	Letter of GBH CPAs, PC, dated August 6, 2018 (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed on August 6, 2018 (File No. 001-36351)).
21.1	Subsidiaries of the Company.*
23.1	Consent of Marcum LLP.*
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 with confidential portions omitted pursuant to a request for confidential treatment. The omitted portions have been separately filed with the SEC.

* Filed herewith.

Table of Contents

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 13, 2020

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

Date: March 13, 2020

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 13, 2020
/s/ Michael J. Valentino Michael J. Valentino	Director and Executive Chairman of the Board	March 13, 2020
/s/ Gary Balkema Gary Balkema	Director	March 13, 2020
/s/ Anthony Bartsh Anthony Bartsh	Director	March 13, 2020
/s/ Robert Casale Robert Casale	Director	March 13, 2020
/s/ Kirk Calhoun Kirk Calhoun	Director	March 13, 2020
/s/ John W. Hadden II John W. Hadden II	Director	March 13, 2020

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

PLx Pharma Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): its common stock, par value $0.001 per share ("Common Stock"). The following is a summary of the material terms of the Common Stock. This summary is qualified in its entirety by reference to the Company's Amended Certificate of Incorporation, as amended (the "Charter"), and Amended and Restated Bylaws (the "Bylaws"), which are incorporated herein by reference as Exhibit 3.1 and Exhibit 3.3, respectively, to the Company's Annual Report on Form 10-K of which this Exhibit 4.4 is a part. We encourage you to read the Charter, the By-laws and applicable provisions of the Delaware General Corporation Law for additional information.

Description of Common Stock

Authorized Capital Stock

The Company is authorized to issue 100,000,000 shares of Common Stock and 1,000,000 shares of preferred stock, par value $0.001 per share. The Company's Board of Directors (the "Board") is authorized to provide for the issuance of shares of preferred stock in one or more series and to fix for each such series such voting powers, designations, preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereon, as determined by the Board.

Voting Rights and Requirements

Each share of Common Stock entitles its record holder to one vote on all matters to be voted on by the common stockholders of the Company. Except as otherwise provided by law, actions by the common stockholders of the Company may be approved by a majority vote of the stockholders present at a duly called meeting of the stockholders at which a quorum is present; however, an amendment to the Bylaws by the stockholders requires the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of the capital stock of the Company entitled to vote at a meeting of stockholders, duly called. The Board of the Company may, by majority vote of those present at any meeting at which a quorum is present, amend the Bylaws, or enact such other Bylaws as in their judgment may be advisable for the regulation of the conduct of the affairs of the Company. At all meetings of stockholders for the election of directors (except the Series A Director elected by the holders of the Series A Preferred Stock, voting separately as a class), a majority of the votes cast is sufficient to elect. No provision of the Company's Charter or Bylaws provides for cumulative voting in the case of the election of directors or on any other matter.

In addition to the Company's outstanding common stock, the Company has outstanding options to purchase its common stock held by its employees and directors and additional shares available for issuance under several equity compensation plans, as further described in the Company's periodic reports filed with the SEC.

Dividends and Liquidation Rights

Each holder of Common Stock of the Company is entitled to share pro rata in any dividends paid on the Common Stock out of assets legally available for that purpose, when, and if declared by the Board of the Company. Upon the liquidation, dissolution or winding up of the Company, the assets of the Company shall be distributed pro rata among the holders of Common Stock. However, the aforementioned dividend and liquidation rights are limited and qualified by the Series A Preferred Stock, which has a preference to any such distribution of the assets or funds. Other than the rights described above, the holders of Common Stock have no redemption, preemptive, subscription or conversion rights, nor any rights to payment from any sinking or similar fund, and are not subject to any calls or assessments. There are no restraints in the Charter or Bylaws of the Company on the right of holders of shares of Common Stock to sell or otherwise alienate their shares of stock in the Company, and there are no provisions discriminating against any existing or prospective holder of shares of Common Stock as a result of such security holder owning a substantial amount of securities.

Stock Exchange Listing

The Common Stock is listed on the Nasdaq Capital Market under the trading symbol "PLXP".

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is VStock Transfer, LLC.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement No. 333-204830, 333-230478 and 333-230550 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 13, 2020 relating to the consolidated financial statements of PLx Pharma Inc. as of December 31, 2019 and 2018 and for the years then ended, which report is included in this Annual Report on Form 10-K of PLx Pharma Inc. for the year ended December 31, 2019.

/s/ Marcum LLP

Marcum LLP
Houston, Texas

March 13, 2020

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 13, 2020

/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 13, 2020

/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, 2019 (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 13, 2020

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

Dated: March 13, 2020

/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.