

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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 001-32518



NUO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

23-3011702

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

**207A Perry Parkway, Suite 1
Gaithersburg, MD 20877**

(Address of principal executive offices) (Zip Code)

(240) 499-2680

(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$0.0001 par value

(Title of class)

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 Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer, large accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "

Accelerated filer "

Non-accelerated filer "

Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes " No x

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$39 million based on the closing price reported for such date on the OTC Markets Group OTCQX marketplace.

As of March 20, 2015 the number of shares outstanding of the registrant's Common Stock, \$0.0001 par value, was 125,680,100.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K, to be filed on or before April 30, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K.

NUO THERAPEUTICS, INC.

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Special Note Regarding Forward Looking Statements

Some of the information in this annual report on Form 10-K (the “Annual Report”) (including the section regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations) contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance, or achievements, and may contain the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “the facts suggest,” “will be,” “will continue,” “will likely result” and words of similar import. These statements reflect the Company’s current view of future events and are subject to certain risks and uncertainties as noted in this Annual Report and in other reports filed by us with the Securities and Exchange Commission. The risks and uncertainties are detailed from time to time in reports filed by us with the Securities and Exchange Commission, including Forms 8-K, 10-Q, and 10-K, and include, among others, the following: our limited sources of working capital; our need for substantial additional financing; our history of losses and future expectations; our short history and limited operating experience; our ability to comply with requirements imposed upon us by certain financing agreements, including from Deerfield Management Company, L.P., or Deerfield; the liquidity of our common stock resulting from its trading on the OTC Markets Group OTCQX marketplace; our reliance on several single source suppliers; our ability to secure additional debt or equity financing; our ability to protect our intellectual property; our compliance with governmental regulations; the success of our clinical trials; our ability to contract with healthcare providers; our ability to successfully sell and market the Aurix System; our ability to secure Medicare reimbursements at adequate levels; the acceptance of our products by the medical community; our ability to attract and retain key personnel; our ability to successfully pursue strategic collaborations to help develop, support or commercialize our products; and the volatility of our stock price. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results could differ materially from those anticipated in these forward-looking statements.

The risks included here are not exhaustive. Other sections of this report may include additional factors which could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for management to predict all such risk factors, nor can it assess the impact of all such risk factors on our business, or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

The Company undertakes no obligation and does not intend to update, revise or otherwise publicly release any revisions to its forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events.

Trademark Notice

The Company owns or has rights to various copyrights, trademarks and trade names used in its business, including, but not limited to, Aurix, Angel and AutoloGel. This Annual Report also includes discussions of or references to other trademarks, service marks and trade names of other companies. Other trademarks and trade names appearing in this Annual Report are the property of the holder of such trademarks and trade names.

PART I

ITEM 1. Business

Corporate Overview

Nuo Therapeutics, Inc. is a Delaware corporation organized in 1998 under the name Informatix Holdings, Inc. As used in this report, the terms “we,” “us,” “Nuo Therapeutics” and the “Company” refer to Nuo Therapeutics, Inc., and its predecessors, subsidiaries and affiliates, unless the context indicates otherwise. In 1999, Autologous Wound Therapy, Inc., or AWT, an Arkansas Corporation, merged with and into Informatix Holdings, Inc. and the name of the surviving corporation was changed to Autologous Wound Therapy, Inc. In 2000, AWT changed its name to Cytomedix, Inc., or Cytomedix. In 2001, Cytomedix, filed for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code, after which Cytomedix was authorized to continue to conduct its business as a debtor and debtor-in-possession. Cytomedix emerged from bankruptcy in 2002 under a Plan of Reorganization. At that time, all of Cytomedix’s securities or other claims against or equity interest in Cytomedix, were canceled and of no further force or effect. Holders of certain securities, other claims or equity interests were entitled to receive new securities from Cytomedix in exchange for their securities, other claims or equity interests prior to the bankruptcy. In September 2007, Cytomedix received 510(k) clearance for the Aurix™ System, or Aurix (formerly known as the AutoloGel™ System), from the U. S. Food and Drug Administration, or FDA. In April 2010, Cytomedix acquired the Angel® Whole Blood Separation System, referred to as Angel or the Angel® Business, from Sorin Group USA, Inc., or Sorin. In February 2012, Cytomedix, acquired Aldagen, Inc., or Aldagen, a privately held cell-therapy company located in Durham, NC. In 2014, Cytomedix changed its name to Nuo Therapeutics, Inc. Aldagen is a wholly-owned subsidiary of Nuo Therapeutics. Our principal offices are located at 207A Perry Parkway, Suite 1, Gaithersburg, Maryland 20877; and our telephone number is (240) 499-2680.

Financial Information about Segments and Geographic Regions

Through December 31, 2014, Nuo Therapeutics had only one operating segment. Nuo Therapeutics primarily operates in the United States (“U.S.”). Revenues from sales generated outside the U.S. are separately presented in this report under Item 8, Financial Statements and Supplementary Data.

Our Business

Nuo Therapeutics is a regenerative therapies company developing and marketing products within the U.S. and internationally through our strategic partners. We commercialize innovative cell-based technologies that harness the regenerative capacity of the human body to trigger natural healing. The use of autologous biological therapies for tissue repair and regeneration is part of a transformative clinical strategy designed to improve long term recovery in complex chronic conditions with significant unmet medical needs.

Our current commercial offerings are centered on our point of care platform technologies for the safe and efficient separation of blood and bone marrow to produce platelet based therapies or cell concentrates. Presently, we promote two distinct platelet rich plasma (“PRP”) technologies, the Aurix System for wound care, and the Angel concentrated Platelet Rich Plasma (“cPRP”) System for orthopedics and cardiovascular markets. Our sales are predominantly (approximately 73%) in the U. S., where we sell our products through a combination of direct sales representatives and a distribution partner. Growth drivers in the U.S. include Medicare coverage for the treatment of chronic wounds under a National Coverage Determination (“NCD”) when registry data is collected under Coverage with Evidence Development (“CED”) and a worldwide distribution and licensing agreement that allows our partner to promote the Angel System for all uses other than wound care.

The Aurix™ System (formerly the AutoloGel System)

In October 2014, we relaunched our AutoloGel chronic wound care system under the Aurix™ brand, as a part of our marketing plan for the commercialization of Aurix™ in the U.S. chronic wound care market.

The Aurix™ System is a point of care device for the production of a platelet based bioactive wound treatment derived from a small sample of the patient's own blood. It is cleared by the FDA for use on exuding wounds and is currently marketed in the U.S. chronic wound market. The most significant growth driver for this system is the 2012 NCD from the Centers for Medicare and Medicaid Services, or CMS, which reversed a twenty year-old non-coverage decision for autologous blood products used in wound care. Using the patient's own platelets as a therapeutic agent, Aurix™ harnesses the body's natural healing processes to deliver growth factors, chemokines and cytokines known to promote angiogenesis, and to regulate cell growth and the formation of new tissue. Once applied to the prepared wound bed, the biologically active platelet gel can restore the balance in the wound environment, to transform a non-healing wound to a wound that heals naturally. There have been nine peer-reviewed scientific and clinical publications demonstrating the effectiveness of Aurix (under the AutoloGel name) in the management of chronic wounds since the device and gel were cleared by the FDA in 2007.

In October 2014, CMS denied a fifth data collection protocol that was designed to simplify the data collection process. In response, the Company negotiated amendments to existing protocols 2-4 that will accomplish similar improvements in efficiency. These amendments were approved by CMS and implemented in January 2015. In the final rule, CMS also made it clear that this payment level will be reviewed annually, allowing for the incorporation of resource utilization data collected throughout 2014 to potentially change future payment decisions. In a related decision to control Medicare spending for wound care, CMS finalized rules that will package the payment for various skin substitute products into the payment for the associated clinical procedures. When fully implemented, these revised payment amounts and procedures are expected to enhance the Company's economic value proposition of Aurix™ in the market for advanced wound care therapies. In addition, CMS issued the final payment rules for the Medicare Physician Fee Schedule, or MPFS, directing Medicare Administrative Contractors (MACs), to set the payment rates for reimbursement claims based on charges submitted by physician offices. The MACs will determine these payments through the use of invoices and other documentation provided by physician offices. This payment level is consistent with the proposed rule announced by CMS in July 2014. These rules took effect January 1, 2014. The CMS rules for the 2015 calendar year went into effect on January 1, 2015 and do not contain any material changes from the 2014 rules.

We have made research advancements on a next generation Aurix™ PRP Preparation device, which is designed to enhance the separation of blood components to provide the added convenience and effectiveness that treating clinicians are looking for at the point of care. Importantly, the new device will allow for the whole blood collection and the separation of the PRP to be accomplished with a single specially designed closed-syringe system that maintains an aseptic environment. We believe that this will streamline the process and improve safety and ease-of-use. We have completed sterilization studies, and expect to file a 510(k) application with the FDA upon the completion of platelet characterization and validation studies. We plan to conduct market research in the future to confirm the market viability of this next generation product.

In August 2014, we partnered with Net Health to develop functionality in Net Health's WoundExpert software that enables collection of patient data for our CED program. Under this arrangement, we will work with Net Health to develop functionality within the WoundExpert software to allow clinics to identify patients who may qualify for the Aurix™ CED program and track the necessary data points for those patients. CMS relies on clinical evidence to determine whether particular items and services are reasonable and necessary. It developed the Coverage with Evidence Program to address coverage of items and services that were believed to be promising but whose ultimate impact on Medicare beneficiary health outcomes remained unconfirmed. The CED program requires more evidence to be collected to determine the full potential benefit of new technologies. Under the CED program, Medicare reimburses for promising new technologies while further evidence is developed.

The Company will continue to pursue potential partnerships and commercial agreements for Aurix with interested parties.

Medicare Reimbursement

On October 4, 2011 CMS accepted a formal request by Nuo Therapeutics to reopen and revise Section 270.3 of the “Medicare NCD Manual”, which addresses Autologous Blood-Derived Products for Chronic Non-Healing Wounds. Subsequently, a NCD for autologous PRP with data collection as a condition of coverage was issued by CMS in August 2012. On March 1, 2013, CMS approved four data collection protocols submitted by the Company. On June 10, 2013, CMS established HCPCS Code G0460 (Autologous PRP for ulcers)¹ for payment effective July 1, 2013 for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical trial. This determination permits data collection with reimbursement. On December 2, 2013 CMS designated that this code be paid at a national average rate of \$411 per treatment encounter under the Hospital Outpatient Prospective Payment System, or HOPPS. We anticipate that this payment decision will expand the reimbursement coverage for Aurix and allow healthcare providers in the outpatient setting to treat a broad patient population that includes those with diabetic foot ulcers, pressure ulcers and venous ulcers. In the final rule, CMS also made it clear that this payment level will be reviewed annually, allowing for the incorporation of resource utilization data collected throughout 2014. In the final payment rules that became effective January 1, 2015, CMS increased the HOPPS payment rate from \$411 to \$430. In a related decision to control Medicare spending for wound care, CMS finalized rules that will package the payment for various skin substitute products into the payment for the associated clinical procedures. When fully implemented, these revised payment amounts and procedures are expected to enhance the economic value proposition of Aurix in the market for advanced wound care therapies. In addition, CMS issued the final payment rules for the MPFS, directing MACs, to set the payment rates for claims for Aurix based on charges submitted by physician offices. The MACs will determine these payments through the use of invoices and other documentation provided by physician offices. These rules took effect January 1, 2014. The CMS rules for the 2015 calendar year took effect on January 1, 2015 and do not contain any material changes from the 2014 rules.

Market

Chronic wounds account for an estimated \$6 billion to \$15 billion annually in U.S. health care costs with an estimated 6.5 million chronic skin ulcers caused by pressure, venous stasis, or diabetes mellitus. To date, sales have primarily been in sub-markets with established payment pathways for Aurix such as Long-Term Acute Care Hospitals (“LTAC”), Veterans Administration Facilities, and certain state Medicaid Agencies. With Medicare coverage now secured for Aurix, in 2015 we plan to expand into outpatient wound care centers. CED is expected to allow the Company to expand the use of Aurix while continuing to demonstrate effectiveness in diabetic ulcers, pressure ulcers, and venous ulcers. Over time, we also plan to further expand the target customer base by seeking reimbursement from commercial third party payors.

Competition

Aurix is the only platelet based system cleared by the FDA for the management of chronic wounds. We believe the formulation is optimized to increase the benefits of healing when used on chronic wounds. Specifically, it produces a platelet-based bioactive gel with a physiologically relevant concentration of platelets at 1.3x baseline, which we believe is the optimal concentration for wound management. All other PRP systems produce platelet concentrates at 3 - 14x baseline. Furthermore, it has a preparation time of five minutes which optimizes its use as a point-of-care therapy. Aurix acts as a biologic healing stimulant to restart the healing process in chronic wounds. Non-healing ulcers are the most frequent cause of amputation. A randomized controlled trial (RCT) with Aurix demonstrated a 81% complete healing rate in common sized diabetic foot ulcers. Over the past few years, multiple additional data sets have been published in peer-reviewed journals and numerous poster and oral presentations have been presented at leading wound care conferences. However, we face a challenging competitive environment as the chronic wound market has many therapies that directly compete with Aurix, including alternative and, older therapies that have established habitual use patterns and provider contracts to encourage standardized use. Acceptance of new products, like Aurix, has been slow. Also, several suppliers to the chronic wound market have large market share and significant resources to expend on sales and marketing efforts. However, we believe that the positive clinical data amassed to date and the recently obtained Medicare CED-coverage will position the Company to increase sales and penetrate markets.

¹ Autologous PRP for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment.

Post-Marketing Surveillance Study

Following the positive clearance decision from the FDA, we agreed to conduct a post-market surveillance program (The Aurix Post-marketing Surveillance, or TAPS) to further analyze the safety profile of bovine thrombin as used in the Aurix System. The TAPS program was initiated in 2008 and the Company began enrolling patients in the TAPS program in late 2009. Since the inception of TAPS, the Company has enrolled 120 patients, noting no adverse events. As a result of this and other positive safety data, the Company has suspended further enrollment in this surveillance program.

Product Development

We have made research advances on a next generation Aurix PRP preparation device, enhancing the separation of blood components to provide the added convenience and effectiveness that treating clinicians are looking for at the point of care. Importantly, the new device allows for the whole blood collection and the separation of the PRP to be accomplished with a single specially designed closed syringe system that maintains an aseptic environment. This streamlines the process and improves safety and ease-of-use. The sterilization studies are complete and we expect to file a 510(k) application with the FDA upon the completion of platelet characterization and validation studies.

Other Developments

In September 2009, we entered into a license and distribution agreement with Millennia Holdings, Inc. ("Millennia") for the Company's Aurix System in Japan. Since then, Millennia has been collecting and publishing clinical data for regulatory purposes and expanding the utilization of Aurix throughout their network. The diabetic population in Japan is estimated to be approximately seven million adults. Millennia has assisted the Company in securing a partner to address widespread distribution in Japan.

In January 2015 we granted to Rohto Pharmaceutical Co., Ltd. ("Rohto") a royalty bearing, nontransferable, exclusive license, with limited right to sublicense, to use certain of the Company's intellectual property for the development, import, use, manufacturing, marketing, sale and distribution for all wound care and topical dermatology applications of the Aurix system and related intellectual property and know-how in human and veterinary medicine in Japan in exchange for an upfront payment from Rohto of \$3.0 million (which is reduced by the \$1.5 million payment to Millennia Holdings, as set forth below). The agreement also contemplates additional royalty payments based on the net sales of Aurix in Japan and an additional future cash payment in the event specific milestones are met.

In connection with and effective as of the entering into the Rohto Agreement, we executed Amendment No. 5 to the Licensing and Distribution Agreement with Millennia dated September 10, 2009, as subsequently amended to terminate the Millennia Agreement and to allow us to transfer the exclusivity rights from Millennia to Rohto. In connection with this amendment we paid a one-time, non-refundable fee of \$1.5 million to Millennia upon our receipt of the \$3.0 million upfront payment from Rohto and may be required to pay certain future royalty payments to Millennia based upon net sales in Japan. Millennia has been instrumental in establishing the advanced wound care market in Japan, and will continue to work with Rohto to develop the market for Aurix. Further, Rohto has assumed all responsibility for securing the Marketing Authorization ("MA") from Japan's Ministry of Health, Labour and Welfare ("MHLW"), while we will provide relevant product information, as well as clinical and other data to support Rohto's MA application.

Angel[®] Product Line

We acquired the Angel cPRP System from Sorin in April 2010. This system is designed for single-patient use at the point of care, and provides a simple, and flexible, means for producing quality PRP and platelet poor plasma, or PPP, from whole blood or bone marrow. The Angel cPRP System is a multi-functional cell separation device which produces cPRP for use in the operating room and clinic and is used in a range of orthopedic and cardiovascular indications. The Angel System is a point of care device for the production of a concentrated, aseptic platelet-based bioactive therapy derived from a small sample of the patient's own blood. The resulting cPRP is applied during orthopedic procedures to facilitate healing. An additional indication from the FDA for processing bone marrow and additional sales resources is expected to contribute to the sales growth of Angel. The addition of an indication to process bone marrow, based on a 510(k) clearance from FDA achieved in 2012, provides a safe alternative to bone morphogenetic protein, or BMP, solutions used in orthopedic surgery.

The Angel product line also includes ancillary products such as phlebotomy and applicator supplies, and activAT®. ActivAT is designed to produce autologous thrombin serum from PPP and is sold exclusively in Europe and Canada, where it provides a safe alternative to bovine-derived products.

In August 2013, we entered into a Distributor and License Agreement with Arthrex, Inc., or Arthrex, a privately held Florida based company. Under the terms of this agreement, Arthrex obtained the exclusive rights to sell, distribute, and service our Angel Concentrated Platelet System and activAT throughout the world for all uses other than chronic wound care. We granted Arthrex a limited license to use our intellectual property as part of enabling Arthrex to sell these products. Arthrex purchases these products from us to distribute and service. Arthrex pays us a certain royalty rate based upon volume of the products sold. The exclusive nature of Arthrex's rights to sell, distribute and service the products is subject to certain existing supply and distribution agreements such that Arthrex may instruct us to terminate or not renew any of such agreements. In addition, Arthrex's rights to sell, distribute and service the products is not exclusive in the non-surgical dermal and non-surgical aesthetics markets.

Product Development

In November 2012, we obtained a second 510(k) clearance for our Angel cPRP System for processing a mixture of blood and bone marrow aspirate. PRP produced from either blood or a mixture of bone marrow aspirate may be combined with bone graft material and used in appropriate orthopedic procedures, such as spinal fusion, healing of nonunion bone fractures and other bone grafting applications.

During 2014 and 2015, we devoted substantial resources to enhancing and improving the Angel Product Line to meet new and additional regulatory requirements. During the period that we have been implementing the modifications, we were unable to meet our customer's demand for Angel devices. As a result, our sales were lower than expected and in addition, we incurred a charge to earnings of \$600,000 during the year ended December 31, 2014, reflecting our expected costs for refurbishment and design improvements for the units in circulation. Although we believe that we have completed all the necessary design modifications to the Angel Products, we cannot be sure that we will not continue to experience delays and additional costs in the future.

Market

Angel was cleared by the FDA in August 2005 and is used primarily in surgical settings, for separation of whole blood into red cells, PPP and PRP. In 2013 the global platelet rich plasma market was valued at approximately \$160 million and it is projected to grow at a compounded annual growth rate of 11.9% from 2014 to 2020

The 510(k) clearance for bone marrow aspirate processing increases our ability to support and advance markets within personalized regenerative medicine. Samples of bone marrow aspirate are routinely collected using a needle to obtain a small amount of the soft sponge like fluid found inside of bones. Aspirated bone marrow is frequently used with bone grafting procedures and bone grafts are widely used to treat conditions associated with bone loss and delayed union and nonunion fractures. In the U.S., approximately 400,000 spinal fusion procedures are performed each year and the application of bone marrow or bone marrow concentrates has been the historical gold standard. Concentrated PRP produced from blood and bone marrow may be used in up to 90% of spinal fusion procedures. The worldwide market for tissue-engineered orthopaedic products is estimated to be approximately \$850 million annually, including the U.S market estimated at approximately \$700 million annually.

Competition

We believe Angel has several competitive advantages compared with other commercially available PRP systems including: (1) high platelet yields, (2) significant reduction in pro-inflammatory cells, (3) rapid processing time, (4) adjustable hematocrit from 0% – 25%, and (5) flexible final cPRP volumes. Proprietary software automatically adjusts the separation parameters to deliver a consistent, high-quality product. Closed system processing helps assure a safe and aseptic product.

A number of our competitors are larger companies, with established market share and possess greater resources than we have to expand sales and marketing efforts. Companies with competing systems include Harvest Technologies (a subsidiary of Terumo), Biomet, and Arterioocyte. We believe the advantages listed above, in addition to our partnership with Arthrex, will facilitate an increase in our competitive position and market share.

Suppliers

We use single suppliers for several components of the Angel and Aurix™ product lines. We outsource the manufacturing of various products, including component parts for Angel, to contract manufacturers. While we believe these manufacturers to demonstrate competency, reliability and stability, there can be no assurance that one or more of them will not experience an interruption or inability to provide us with the products needed to satisfy customer demand.

Additionally, while most of the components of Aurix™ are generally readily available on the open market, a reagent, bovine thrombin, is available exclusively through Pfizer, with whom we have an established vendor relationship.

ALDH br, or Bright Cell, Technology and Development Pipeline

We acquired the ALDHbr, or Bright Cell, technology as part of our acquisition of Aldagen in February 2012. The Bright Cell technology is a novel approach to cell-based regenerative medicine with potential clinical indications in large markets with significant unmet medical needs, such as peripheral arterial disease. The Bright Cell technology is unique in that it utilizes an intracellular enzyme marker to facilitate fractionation of essential regenerative cells from a patient's bone marrow. This core technology was originally licensed by Aldagen from Duke University ("Duke") and Johns Hopkins University ("JHU"). The proprietary bone-marrow fractionation process identifies and isolates active stem and progenitor cells expressing high levels of the enzyme aldehyde dehydrogenase, or ALDH, which is a key enzyme involved in the regulation of gene activities associated with cell proliferation and differentiation. These autologous, selected biologically instructive cells have the potential to promote the repair and regeneration of multiple types of cells and tissues, including the growth of new blood vessels, or angiogenesis, which is critical to the generation of healthy tissue.

Reorganization of Research and Development Operations related to ALD-401

In September 2013, we announced our decision to begin a strategic reorganization of our research and development operations that involved discontinuing clinical trials of ALD-401, which focused on the RECOVER-Stroke trial and one component of the technology present in the ALDH Bright Cell platform. This discontinuation was limited to the above mentioned clinical trial of RECOVER-Stroke, and does not represent our discontinuation of efforts to develop and commercialize Bright Cell technology. Following the January 2014 completion of the trial enrollment in the RECOVER-Stroke trial, in May 2014 we announced preliminary efficacy and safety results of our RECOVER-Stroke Phase 2 clinical trial in patients with neurological damage arising from ischemic stroke and treated with ALD-401. Observed improvements in the primary endpoint (mean modified Rankin Score or mRS) of the trial were not clinically or statistically significant. In light of this outcome, we discontinued further funding of the ALD-401 development program, and in connection therewith, closed our R&D facility in Durham, NC, which supported the development of ALD-401. This decision to close down the facility was in line with the overall realignment of our commercial operations to focus on the wound care market.

Continued Development of Bright Cell Technology

Notwithstanding the discontinuation of further funding of the RECOVER-Stroke clinical trials, we will continue to develop the Bright Cell technology platform for other uses, and will conduct a Phase 1/2 clinical trial in critical limb ischemia (PACE), that is being funded by the National Institutes of Health, and a Phase 1 clinical trial in grade IV malignant glioma following surgery, that is funded by Duke University.

Customer Concentration

In 2014, Nuo Therapeutics recorded sales to approximately 72 customers, including distributors. In 2014, Arthrex accounted for 91% of total product sales. No other single customer accounted for more than 5% of total product sales. Since August 8, 2013, Arthrex accounted for 100% of our Angel sales.

Patents, Licenses, and Property Rights

Nuo Therapeutics relies on a combination of patents, trademarks, trade secrets, and copyright laws, as well as confidentiality agreements, contractual provisions, and other similar measures, to establish and protect its intellectual property.

Historically, the Company has been party to certain royalty agreements relating to its intellectual property under which it pays certain fees, and has acquired additional royalty agreements as part of the acquisition of Aldagen. Currently, the Company is paying royalties under the following agreements:

- The inventor is entitled to receive a royalty equal to 5% of gross profits on revenues generated from reliance on the Worden Patents (U.S. patents 6,303,112 and 6,524,568), covering the formulation of Aurix. In conjunction with the release of a security interest in the applicable patents securing our payment obligations under a royalty agreement, we paid the inventor a lump sum \$500,000 payment in February 2013 in satisfaction of all remaining minimum monthly royalty payments. In addition, the annual maximum royalty payment was raised to \$625,000 from \$600,000 in conjunction with the amendment. Finally, the Company has no annual royalty obligation unless and until the calculated annual royalty obligation exceeds \$100,000 in a given year. This agreement terminates with the expiration of the patents in 2019.
- Under our license agreement, as amended, with JHU, JHU has granted us an exclusive, worldwide license, under its patents relating to flow sorting of stem cell populations based on a fluorescent ALDH substrate, or the JHU Patents. Under the terms of the JHU license agreement, as amended, we are obligated to pay a 3% royalty on revenues relating to therapeutic products based on the JHU Patents, and up to 7% on revenues relating to other products based on the JHU patents, subject to an annual minimum of \$10,000. We must also pay up to \$222,500 in the aggregate upon the satisfaction of specified development milestones. The Company bears all costs to maintain the patents. This agreement terminates with the expiration of the patents in 2016.
- Under our license agreement with Duke, Duke has granted us an exclusive, worldwide license under its patents and applications that relate to methods for isolating and manufacturing ALDH Bright Cell populations, or the Duke Patents. Under the terms of the Duke license agreement, we are obligated to pay up to a 1% royalty to Duke on all revenues relating to the Duke Patents, subject to an annual minimum of \$5,000 (which will increase to \$25,000 upon the achievement of specified development and commercialization milestones). The Company bears all costs to maintain the patents. This agreement terminates with the expiration of the patents in 2018.

Nuo Therapeutics' patent strategy, designed to maximize value, seeks to: (i) assist the Company in establishing significant market positions for its products, (ii) attract strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could include milestone payments to the Company, and (iii) generate revenue streams via out-licensing agreements.

Including the Aldagen patents, Nuo Therapeutics' current patent portfolio consists of domestic and international patents that generally fall into the following families:

- Process, formulation, and methods for utilizing platelet releasates to heal damaged tissue;
- Design patents relating to our devices;
- Biomarkers for wound-healing treatment efficacy;
- Peptides with anti-inflammatory properties;
- Devices and processes for the production of autologous thrombin;

- Process and methods for isolating and manufacturing ALDH Bright Cell populations; and
- Specific chemistries for isolating and manufacturing ALDH Bright Cell populations.

The above patent families encompass the Company's Angel, activAT, and Aurix products, as well as the CT-112 anti-inflammatory peptide, homologous growth factors, wound-healing biomarkers, ALDH Bright Cell populations, and several other potential therapies. Nuo Therapeutics is continually assessing new opportunities to create or in-license other intellectual property assets. These patents have expiration dates ranging from 2015 to 2027. The peptides with anti-inflammatory properties international patent expired in 2014, the US patent expires in 2015. The expiration of this patent is not expected to have an impact on our results of operations.

Business Strategy

We continue to focus on the research, development, marketing and commercialization of products and product candidates in the U.S. and internationally, with a particular emphasis on the wound care market. We believe that the market for innovative cell-based technologies that harness the regenerative capacity of the human body to trigger natural healing, represents a significant opportunity from both a medical and a business perspective. Our immediate goal is to successfully commercialize our Aurix System (formerly the AutoloGel System), Angel Product Line, and continue to develop product candidates utilizing the Bright Cell technology platform. Key elements of our strategy to achieve these goals include:

- To advance the commercialization of our Aurix System product for the treatment of chronic wound care in the U.S., we have recruited and deployed a direct sales force focused on the Hospital Outpatient Specialized Wound Care market as well as the Veterans Affairs medical system. To support our direct sales organization we have also hired marketing and field-based reimbursement professionals. These three groups compose the majority of the commercial organization. In addition to the commercial team, we have also hired and deployed a team of clinical professionals. The clinical team is focused on both support of health care providers in their use of Aurix as well as facilitating the collection of the clinical data required to fulfill the Aurix Medicare Coverage with Evidence Development (CED) requirements. While we are currently focused on the commercialization of our FDA cleared Aurix System in the U.S., an important priority for us is to secure strategic resources to support the continued development and commercial introduction of our products in markets outside the U.S. In furtherance thereof, in January 2015 we signed an exclusive licensing and distribution agreement for the Aurix System with Rohto providing them with an exclusive license and the right to develop and commercialize Aurix in the Japanese market. The agreement also contemplates additional royalty payments based on the net sales of Aurix in Japan and an additional future cash payment in the event specific milestones are met. Rohto has assumed all responsibility for securing the MA from Japan's MHLW, while we will provide relevant product information, as well as clinical and other data to support Rohto's MA application.
- To advance the worldwide commercialization of our Angel Product Line as a point-of-care device for the production of a concentrated, aseptic platelet-based bioactive therapy derived from a small sample of a patient's own blood to promote healing, for use in the operating room and clinic, as well as for use in a range of orthopedic and cardiovascular indications we have entered into a distribution agreement with Arthrex, an orthopedic supply company. The terms of the worldwide distribution agreement calls for Arthrex to promote the Angel Product Line through their sales team as part of their day to day promotional efforts.
- To advance the research and development of our Bright Cell technology through strategic partnerships with leading research universities, such as JHU and Duke.
- An important priority for us is to strengthen our long-term financial position. We will require significant additional capital over time to advance our development programs, support the commercialization or introduction of our approved products, support our operations and maximize stockholder value. See, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

- o We plan to continue to carefully manage our cash resources and will seek additional capital, potentially, but not limited to future debt and equity financings, as we deem necessary to maintain and strengthen our financial position.
- o In addition, as noted above, we expect that strategic alliances will play an important role in strengthening our financial position as well as our capabilities as we advance our products and product candidates.

We plan to continue to evaluate our product and product candidates, and focus our efforts on commercially viable products in the wound care market, and to further develop our Bright Cell technology for commercialization. In September 2013, we announced our decision to begin a strategic reorganization of the Company's research and development operations related to clinical trials for ALD-401 based RECOVER-Stroke trial, which also included a component of the ALDH Bright Cell platform. Following the January 2014 completion of the trial enrollment in the RECOVER-Stroke trial, in May 2014 we announced preliminary efficacy and safety results of our RECOVER-Stroke Phase 2 clinical trial in patients with neurological damage arising from ischemic stroke and treated with ALD-401. Observed improvements in the primary endpoint (mean modified Rankin Score, or mRS) of the trial were not clinically or statistically significant. In light of this outcome, we discontinued further funding of the ALD-401 development program and closed our R&D facility in Durham, NC. The discontinuation of the ALD-401 RECOVER-Stroke trial does not affect our other development efforts related to our Bright Cell technology, which efforts remain active. The ongoing development of the Bright Cell technology is being primarily funded and fully conducted by outside partners.

Government Regulation

Government authorities in the U.S., Canada, the European Union, and other countries extensively regulate pharmaceutical products, biologics, and medical devices. The Company's products and product candidates are subject to clearance and monitoring by the governing bodies prior to and during the marketing and distribution of product. Regulatory requirements apply to, but are not limited to, research and development, safety and efficacy, clinical studies, manufacturing, labeling, distribution, marketing, and the import and export of products. Before a product candidate is approved by the governing bodies for commercial marketing, rigorous preclinical and human clinical testing is conducted to determine the safety and efficacy or effectiveness of the product. If the Company fails to comply with the applicable laws and regulations at any time during the product development process, approval process, or during commercialization, it may become subject to administrative and/or judicial sanctions. These sanctions may include, but are not limited to, refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of the Company's operations, injunctions, fines, civil penalties and/or criminal prosecution. Any enforcement action could have a material adverse effect on the Company.

Medical Device Regulation

The Company currently manufactures and distributes the Aurix and Angel cPRP systems. As such, these and future products manufactured and/or distributed by the Company may be subject to regulations by the applicable governing bodies, including but not limited to, the FDA, Health Canada, the European Medicines Agency, the Japanese Ministry of Health & Welfare, and other regulatory agencies. The Company currently has modest operations and business development initiatives outside of the U.S. Each of the governing bodies, noted above, serve a similar function as the FDA. As such, the Company and its products and product candidates are subject to the regulations enforced by the outside governing bodies. These regulations include, but are not limited to, product clearance, documentation requirements, good manufacturing practices and medical device reporting. Labeling and promotional activities are also subject to regulation by the U.S. Federal Trade Commission, in certain circumstances. Current enforcement policies prohibit the marketing of approved medical devices for unapproved uses. Each governing body reviews the labeling and advertising of medical devices to ensure that unapproved uses are not promoted. Before a new medical device can be introduced to the market, the manufacturer must obtain clearance or approval from the applicable regulatory agency, depending upon the device classification. In the U.S., medical devices are classified into one of three classes — Class I, II or III. The regulations enforced by the FDA and/or the appropriate governing bodies to the medical device(s) provide reasonable assurance that the device is safe and effective. In the U.S., Class I devices are non-critical products that the FDA believes can be adequately regulated by "general controls" which include provisions relating to labeling, manufacturer registration, defect notification, records and reports, and current good manufacturing practices ("cGMP") based on the FDA's Quality Systems Regulations. Most Class I devices are exempt from pre-market notification and some are also exempt from cGMP requirements. Class II devices are products for which the general controls of Class I devices, by themselves, are not sufficient to assure safety and effectiveness and, therefore, require additional controls. Additional controls for Class II devices include performance standards, post-market surveillance patient registries, and the use of FDA guidelines. Standards may include both design and performance requirements. Class III devices have the most restrictive controls and require pre-market approval by the FDA. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices. All of the governing bodies with responsibility over the Company's products have the ability to inspect medical device manufacturers, order recalls of medical devices, seize non-complying medical devices, and to criminally prosecute violators.

Section 510(k) of the Federal Food, Drug and Cosmetic Act requires individuals or companies manufacturing medical devices intended for human use to file a notice with the FDA at least ninety days before intending to introduce the device into the market. This notice, commonly referred to as a 510(k), must identify the type of classified device into which the product falls, the class of that type, and a specific product already being marketed or cleared by the FDA and to which the product is “substantially equivalent”. In some instances, the 510(k) must include data from human clinical studies to establish “substantial equivalence”. The FDA must agree with the claim of “substantial equivalence” before the device can be marketed. The statutory time frame for clearance of a 510(k) is ninety days, though it often takes longer. Nuo Therapeutics currently markets only products that are subject to 510(k) clearance.

The Company currently markets the Aurix System Centrifuge II, the Aurix Wound Dressing Kit, Aurix Reagent Kit, and the Angel cPRP System. Each System’s component is a legally-marketed product that has been cleared by FDA and/or the appropriate governing body. The Aurix System Centrifuge II, when used with the Aurix Wound Dressing Kit and Aurix Reagent Kit, are suitable for use on exuding wounds such as leg ulcers, pressure ulcers and diabetic ulcers, and for the management of mechanically or surgically-debrided wounds. The Angel cPRP System consists of the Angel system centrifuge, the Angel cPRP Processing Set, the Whole Blood Access Kit, and the activAT Autologous Thrombin Kit, if applicable. The Angel cPRP System has been cleared for the separation of whole blood or a small amount of whole blood and bone marrow into red cells, PPP and PRP.

In April 2010, the Company acquired the Angel cPRP System (formerly known as the Angel Whole Blood Separation System) from Sorin. The transfer and distribution of the product is an on-going process that is subject to FDA, Health Canada, European Medicines Agency and other regulations specific to the individual marketed areas. The Angel cPRP System was granted FDA 510(k) clearance for processing blood and bone marrow aspirate in November 2012. It received similar clearances from the European and Australian regulatory authorities in November 2012 and February 2013, respectively.

As a specification developer, manufacturer and distributor of medical devices, Nuo Therapeutics is subject to and complies with, among other standards and regulations, 21 C.F.R. of the Food, Drug and Cosmetic Act, ISO 13485, and the Medical Device Directive. As a manufacturer and distributor of medical devices, the Company, and in some instances its subcontractors, is required to register its facilities and products manufactured annually with the appropriate governing bodies and certain state agencies. We are also subject to restrictions on the use of lead and other substances that apply to specified electronic products put on the market in the European Union as of July 1, 2006 (Restriction of Hazardous Substance Directive, or RoHS). Additionally, the Company is subject to periodic inspections by the governing bodies to assess compliance with cGMP regulations. Facilities may also be subject to inspections by other federal, foreign, state or local agencies. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Bio-pharmaceutical Product Regulation

The Company's ALDH Bright Cells product candidates, acquired from Aldagen in 2012, and other bio-pharmaceuticals it may develop, are also regulated by the FDA. Under the U.S. regulatory scheme, the development process for new such products can be divided into two distinct phases:

- **Preclinical Phase.** The preclinical phase involves the discovery, characterization, product formulation and animal testing necessary to prepare an Investigational New Drug application, or IND, for submission to the FDA. The IND must be accepted by the FDA before the product candidate can be tested in humans. The review period for an IND submission is thirty days, after which, if no comments are made by the FDA, the product candidate can be studied in Phase I clinical trials. Certain preclinical tests must be conducted in compliance with the FDA's good laboratory practice regulations and the U.S. Department of Agriculture's Animal Welfare Act.
- **Clinical Phase.** The clinical phase of development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the product candidate in humans, as well as, the ability to manufacture the drug in accordance with cGMP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the efficacy of the product candidate. Each clinical protocol is submitted to the FDA as part of the IND prior to beginning the trial. Each trial is reviewed, approved, and conducted under the auspices of an investigational review board, or IRB, and each trial, with limited exceptions, must include the patient's informed consent. Typically, clinical evaluation involves the following time-consuming and costly three-phase sequential process:

Phase 1. In Phase 1 clinical trials, typically a small number of healthy individuals (although in some instances individuals with the disease or condition for which an indication is being sought for the product candidate are enrolled) are tested with the product candidate to determine safety and tolerability, and includes biological analyses to determine the availability and metabolism of the active ingredient following administration.

Phase 2. Phase 2 clinical trials involve administering the product candidate to individuals who suffer from the target disease or condition to determine the optimal dose and potential efficacy. These clinical trials are well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase 3. Phase 3 clinical trials are performed after preliminary evidence suggesting efficacy of a product candidate has been obtained and safety, tolerability, and an optimal dosing regimen have been established. Phase 3 clinical trials are intended to gather additional information about efficacy and safety that is needed to evaluate the overall benefit-risk relationship and to complete the information needed to provide adequate instructions for the use of the product candidate. Phase 3 trials usually include from several hundred to a few thousand subjects.

Throughout the clinical phase, samples of the product made in different batches are tested for stability to establish shelf-life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed. These trials require scale up for manufacture of increasingly larger batches of bulk chemical. These batches require validation analyses to confirm the consistent composition of the product.

Phase 1, 2, and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend (place on "clinical hold"), or terminate the trials based upon the data accumulated to that point and the agency's assessment of the risk/benefit ratio to the patient. The FDA may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of products under development. Furthermore, IRBs, which are independent entities constituted to protect human subjects at the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials at their respective institutions at any time for a variety of reasons, including safety issues.

After the successful completion of Phase 3 clinical trials, the sponsor of the new bio-pharmaceutical submits a Biologics License Application, or BLA, to the FDA requesting approval to market the product for one or more indications. A BLA is a comprehensive, multi-volume application that includes, among other things, the results of all preclinical studies and clinical trials, information about the product candidate's composition and manufacturing, and the sponsor's plans for manufacturing, packaging, and labeling the drug. Under the Pediatric Research Equity Act of 2003, an application also is required to include an assessment, generally based on clinical study data, of the safety and efficacy of product candidates for all relevant pediatric populations before the BLA is submitted. The statute provides for waivers or deferrals in certain situations. In most cases, the BLA must be accompanied by a substantial user fee. In return, the FDA assigns a goal of 10 months from acceptance of the application to return of a first "complete response," in which the FDA may approve the product or request additional information.

The submission of the application is no guarantee that the FDA will find it complete and accept it for filing. The FDA reviews all BLA's submitted before it accepts them for filing. It may refuse to accept the application and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. After the application is deemed filed and accepted by the FDA, agency staff reviews a BLA to determine, among other things, whether a product is safe and efficacious for its intended use. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its BLA. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of physicians, for review, evaluation, and an approval recommendation. The FDA is not bound by the opinion of the advisory committee. Products that successfully complete BLA review and receive clearance (i.e., approval) may be marketed in the U.S., subject to all conditions imposed by the FDA.

Prior to granting approval, the FDA conducts an inspection of the facilities, including outsourced facilities, that will be involved in the manufacture, production, packaging, testing, and control of the product candidate for cGMP compliance. The FDA will not approve the application unless cGMP compliance is satisfactory. If FDA determines that the marketing application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter. The length of the FDA's review may range from a few months to several years.

If the FDA approves the BLA, the product becomes available for physicians to prescribe in the U.S. After approval, the BLA holder is still subject to continuing regulation by the FDA, including record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product, and complying with drug sampling and distribution requirements. In addition, the BLA holder is required to maintain and provide updated safety and efficacy information to the FDA. The BLA holder is also required to comply with requirements concerning advertising and promotional labeling, including prohibitions against promoting any non-FDA approved or "off-label" indications of products. Failure to comply with those requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials, and substantial fines. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval.

Biologics manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP regulations. Facilities may also be subject to inspections by other federal, foreign, state or local agencies. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

In addition, following the FDA approval of a product, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application, including withdrawal or recall of the product from the market or other voluntary or the FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contra-indications. Also, the FDA may require post-market testing and surveillance to monitor the product's safety or effectiveness, including additional clinical studies, known as Phase 4 trials, to evaluate long-term effects.

Other regulatory agencies, including Health Canada and the European Medicines Agency, require preclinical and clinical studies, manufacturing validation, facilities inspection, and post-approval record keeping and reporting similar to FDA requirements. In some instances, data generated for consideration by the FDA may be submitted to these agencies for their consideration for approvals in other countries.

Fraud and Abuse Laws

The Company may also be indirectly subject to federal and state physician self-referral laws. Federal physician self-referral legislation (commonly known as the Stark Law) prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain “designated health services” if the physician or an immediate family member has any financial relationship with the entity. A person who engages in a scheme to circumvent the Stark Law’s referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. The penalties for violating the Stark Law also include civil monetary penalties of up to \$15,000 per referral and possible exclusion from federal health care programs such as Medicare and Medicaid. The Stark Law also prohibits the entity receiving the referral from billing any good or service furnished pursuant to an unlawful referral, and any person collecting any amounts in connection with an unlawful referral is obligated to refund such amounts. Various states have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a health care provider to their patients when referring patients to that provider. Both the scope and exception for such laws vary from state to state.

The Company may also be subject to federal and state anti-kickback laws. Section 1128B (b) of the Social Security Act, commonly referred to as the Anti-Kickback Law, prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid. The Anti-Kickback Law is broad, and it prohibits many arrangements and practices that are otherwise lawful in businesses outside of the health care industry. The U.S. Department of Health and Human Services, or DHHS, has issued regulations, commonly known as safe harbors that set forth certain provisions which, if fully met, will assure health care providers and other parties that they will not be prosecuted under the federal Anti-Kickback Law. Although full compliance with these provisions ensures against prosecution under the Anti-Kickback Law, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Law will be pursued. The penalties for violating the Anti-Kickback Law include imprisonment for up to five years, fines of up to \$250,000 per violation for individuals and up to \$500,000 per violation for companies and possible exclusion from federal health care programs. Many states have adopted laws similar to the federal Anti-Kickback Law, and some of these state prohibitions apply to patients for health care services reimbursed by any source, not only federal health care programs such as Medicare and Medicaid.

In addition, there are two other U.S. health care fraud laws to which the Company may be subject, one which prohibits knowingly and willfully executing or attempting to execute a scheme or artifice to defraud any health care benefit program, including private payers (“fraud on a health benefit plan”) and one which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for health care benefits, items or services. These laws apply to any health benefit plan, not just Medicare and Medicaid.

The Company may also be subject to other U.S. laws which prohibit submitting claims for payment or causing such claims to be submitted that are false. Violation of these false claims statutes may lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in Medicare, Medicaid and other federally funded state health programs. These statutes include the federal False Claims Act, which prohibits the knowing filing of a false claim (or causing the submission of a false claim) or the knowing use of false statements to obtain payment from the U.S. federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim. Suits filed under the False Claims Act can be brought by an individual on behalf of the government (a “qui tam action”). Such individuals (known as “qui tam relators”) may share in the amounts paid by the entity to the government in fines or settlement. In addition certain states have enacted laws modeled after the False Claims Act. “Qui tam” actions have increased significantly in recent years causing greater numbers of health care companies to have to defend false claim actions, pay fines or be excluded from the Medicare, Medicaid or other federal or state health care programs as a result of an investigation arising out of such action.

Several states also have referral, fee splitting and other similar laws that may restrict the payment or receipt of remuneration in connection with the purchase or rental of medical equipment and supplies. State laws vary in scope and have been infrequently interpreted by courts and regulatory agencies, but may apply to all health care products and services, regardless of whether Medicaid or Medicare funds are involved.

Research and Development

Prior to our acquisition of Aldagen in February 2012, the Company focused its resources primarily on the broad commercialization of Aurix, as well as integration and sales growth of the Angel product line. It therefore expended only limited amounts on research and development activities, or R&D. The Company currently has development projects underway to enhance and broaden indications for the Aurix System which will further strengthen our competitive edge in the chronic wound market, and to further develop our Bright Cell technology.

The Company incurred approximately \$2,624,000 and \$3,798,000 in total R&D expenses in 2014 and 2013, respectively, which are primarily related to the ALD-401 RECOVER-Stroke trial, which we discontinued in May, 2014. These figures do not include salaries and wages, which are included in Salaries and Wages in our Statements of Operations, and the allocation of overhead and other indirect costs, which are included in the General and Administrative Expenses line in our Statements of Operations.

Reorganization of Research and Development Operations related to ALD-401

In May 2014 we announced preliminary efficacy and safety results of our RECOVER-Stroke Phase 2 clinical trial in patients with neurological damage arising from ischemic stroke and treated with ALD-401. Observed improvements in the primary endpoint (mean mRS) of the trial were not clinically or statistically significant. In light of this outcome, we discontinued further funding of the ALD-401 development program, and in connection therewith, closed our R&D facility in Durham, NC, which supported the development of ALD-401.

Continued Development of Bright Cell Technology

Notwithstanding the discontinuation of further funding of the RECOVER-Stroke clinical trials, we will continue to develop the Bright Cell technology platform for other uses, and will conduct a Phase 1/2 clinical trial in critical limb ischemia (PACE), that is being funded and managed by the National Institutes of Health, and a Phase 1 clinical trial in grade IV malignant glioma following surgery, that is funded by Duke University. We expect that the majority of the research and development activity for our Bright Cell technology will occur on-site at leading universities with whom we have strategic relationships.

Employees

The Company had approximately 46 employees, all of which are full time employees, including the Company's management at December 31, 2014. The remaining personnel primarily consist of sales and marketing, accounting, clinical, operational, and administrative professionals. None of the Company's employees is covered by a collective bargaining agreement or represented by a labor union. The Company considers its employee relations to be good.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC's website at "http://www.sec.gov." We make available for download free of charge through our website (<http://nuot.com>) our Annual Report on Form 10-K, our quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we have filed it electronically with, or furnished it to, the SEC. Information appearing on our website is not part of this Annual Report.

ITEM 1A. Risk Factors

The Company faces many risks. The risks described below may not be the only risks the Company faces. Additional risks not yet known or currently believed to be immaterial may also impair Nuo Therapeutics' business. If any of the events or circumstances described in the following risks actually occurs, the Company's business, financial condition or results of operations could suffer, and the trading price of its common stock could decline. You should consider the following risks, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision with respect to Nuo Therapeutics securities.

We Have Limited Sources of Working Capital

Working capital required to implement our business plan will most likely be provided by funds obtained through offerings of our equity, debt, debt-linked securities, and/or equity-linked securities, and revenues generated by us. We may not have revenues sufficient to support and sustain our operations or that we would be able to obtain equity/debt financing in the current economic environment. If we do not have sufficient working capital and are unable to generate sufficient revenues or raise additional funds, we may delay the completion of, or significantly reduce the scope of, our current business plan; delay some of our development and clinical or marketing efforts; delay our plans to penetrate the market serving Medicare beneficiaries and fulfill the related data gathering requirement as stipulated by the Medicare CED coverage determination; delay the pursuit of commercial insurance reimbursement for our wound treatment technologies; or postpone the hiring of new personnel; or, under certain dire financial circumstances, cease our operations.

We May Need Substantial Additional Financing

We will need substantial additional capital to fund our operations. To date, we have relied almost exclusively on financing transactions to fund losses from our operations. Our inability to obtain sufficient additional financing would have a material adverse effect on our ability to implement our business plan and, as a result, could require us to significantly curtail or potentially cease our operations. At December 31, 2014, we had cash and cash equivalents of approximately \$15.9 million, total current assets of approximately \$21.9 million and total current liabilities of approximately \$8.5 million. In connection with the convertible credit facility agreement we entered into with Deerfield, or the Deerfield Facility (*See Note 7 - Debt for additional details*), the Company is required to maintain a compensating cash balance of \$5,000,000 in deposit accounts subject to control agreements in favor of the lenders. In March 2015, we received an upfront payment from Rohto of \$3.0 million in exchange for an exclusive license and the right to develop and commercialize Aurix in the Japanese market. In order to do so, we paid a one-time fee of \$1.5 million to Millennia to terminate their September 2009 license and distribution agreement with the Company for the Japanese market. We estimate that our current resources, expected revenue from current products, including additional revenue expected to be generated from our increased marketing efforts, royalty revenue and license fee revenue will be adequate to maintain our operations through at least 2015. However, if we are unable to increase our revenue as much as expected, or at all, we intend to consider implementing all necessary cost saving efforts which may include reductions in force or reduction of sales, marketing and related commercialization activities, to allow us to maintain operations through at least 2015. Based on our current operating plan, we would anticipate needing additional capital in early 2016. If we fail to obtain this funding we may be forced to curtail our operations. Such financing transactions may well cause substantial dilution to our shareholders and could involve the issuance of securities with rights senior to the outstanding shares. Our ability to complete additional financings is dependent on, among other things, the state of the capital markets at the time of any proposed offering, market reception of the Company and the likelihood of the success of its business model, of the offering terms, etc. We may not be able to obtain any such additional capital as we need to finance our efforts, through asset sales, equity or debt financing, or any combination thereof, on satisfactory terms or at all. Additionally, any such financing, if at all obtained, may not be adequate to meet our capital needs and to support our operations. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, our revenues and operations and the value of our Common stock and common stock equivalents would be materially negatively impacted and we may cease our operations.

We Have a History of Losses and Expect to Incur Losses for the Foreseeable Future

We have a history of losses, are not currently profitable, and expect to incur substantial losses and negative operating cash flows in the future. Although, prior to the Aldagen acquisition, we were targeting operational cash flow break-even within the foreseeable future, the acquisition of Aldagen, and the expenditures necessary to fund the discontinued clinical trial and related activities, caused us to continue to generate losses. We may never generate sufficient revenues to achieve and maintain profitability. We will continue to incur expenses at current or increased levels as we seek to expand our operations, pursue development of our technologies, work to increase our sales, implement internal systems and infrastructure, and hire additional personnel. These ongoing financial losses may adversely affect our stock price.

We have a substantial amount of senior indebtedness. The inability to repay such indebtedness would have a material adverse effect on our financial condition and ability to continue as a going concern.

As of the date of this report, we had approximately \$36.5 million of principal owing under senior secured indebtedness, evidenced by a convertible secured note held by Deerfield. The Deerfield Facility is structured as a purchase of senior secured convertible notes, which bear interest at a rate of 5.75% per annum, payable quarterly in arrears in cash or, at our election, registered shares of our common stock; provided, that during the first five quarters following the closing, we have the option of having all, or any portion of accrued interest, added to the principal balance of the Deerfield Facility. The Company elected to have all of the accrued interest added to the principal balance of the Deerfield Facility until September 30, 2015 beginning with interest for the third quarter of 2014. Deerfield has the right, subject to a 9.98% beneficial ownership limitation, to convert the principal amount of the Deerfield Facility into shares of our common stock at a per share price equal to \$0.52. In addition, we granted Deerfield the option to require us to redeem up to 33.33% of the total amount drawn under the Deerfield Facility, together with any accrued and unpaid interest thereon, on each of the 2nd, 3rd and 4th anniversaries of its closing, with the option right triggered upon our net revenues failing to be equal to, or in excess of, certain quarterly milestone amounts. We also granted Deerfield the option to require us to apply 35% of the proceeds received by us in equity-raising transaction(s) to redeem outstanding principal and interest of these senior convertible notes, provided that the first \$10 million so raised by us will be exempt from this put option. The note is secured by substantially all of our assets. In addition, if our net sales for any of the quarters ended September 30, 2015 or December 31, 2015 is less than the amount required by the Deerfield Facility, the lenders thereunder, in their sole discretion, may require us to prepay one-third of the aggregate amount of the first and second disbursements thereunder, together with accrued and unpaid interest thereon, on March 31, 2016. Further, if our net sales for the quarters ended September 30, 2016 or December 31, 2016 is less than the amount required by the Deerfield Facility, the lenders thereunder, in their sole discretion, may require us to prepay one-third of the aggregate amount of the first and second disbursements thereunder, together with accrued and unpaid interest thereon, on March 31, 2017. If we do not have sufficient capital to pay interest and/or repay principal under the notes when they become due, then we would be in default thereunder, which would have a material adverse effect on our business, our ability to raise capital in the future and our ability to continue as a going concern.

We Have a Short Operating History and Limited Operating Experience

We have, only in the past few years, implemented our commercialization strategy for Aurix and have only four years' experience operating the fully integrated Angel and activAT business. Thus, we have a very limited operating history. Continued operating losses, together with the risks associated with our ability to gain new customers for our product offerings, may have a material adverse effect on our liquidity. We may also be forced to respond to unforeseen difficulties, such as a decreased demand for our products and services, downward pricing trends, regulatory requirements and unanticipated market pressures. Since emerging from bankruptcy and continuing through today, we are developing a business model that includes protecting our patent position, addressing our third-party reimbursement issues, developing and executing a sales and marketing program, acquiring synergistic technologies and product lines, developing other technologies covered by, or derived from, our intellectual property, and seeking strategic partnerships. Our current business model may not be able to accomplish our stated goals.

We May Not Be Able to Comply with the Debt Service and Loan Covenant Requirements of the Deerfield Facility Agreement, Which Could Place the Business Assets of the Company in Jeopardy

The Deerfield security agreement, which secures as collateral all of our assets, and which was entered into in connection with the Deerfield Facility, requires interest payments and compliance with certain covenants, including with respect to maintenance of available cash of at least \$5,000,000, product revenue and others. In addition, we will have to recognize continued sales growth to satisfy our requirements under the Deerfield Facility. Failure to comply with the covenants could allow Deerfield to accelerate payment or trigger a default under the agreement, which in turn could allow Deerfield to seize all of our assets if we are unable to make required payments when required. If any key assets are seized, it would have a material adverse effect on the Company, including the complete cessation of operations, and/or bankruptcy.

We Are Traded on the Over-the-Counter Market Which May Decrease the Liquidity of Our Common Stock

Over-the-counter markets are generally considered to be less efficient than, and not as broad as, a stock exchange. There may be a limited market for our stock, which is quoted on the OTCQX, trading in our stock may become more difficult and our share price could decrease. Specifically, shareholders may not be able to resell their shares of common stock at or above the price paid for such shares or at all. In addition, our ability to raise additional capital may be impaired because of the less liquid nature of the over-the-counter markets. We may not be able to complete an equity financing on acceptable terms, or at all, but if we do, the dilution from any equity financing while our shares are quoted on an over-the-counter market could be greater than if we were to complete a financing while our common stock is traded on a national securities exchange. Further, since our stock is not traded on an exchange, we are not eligible to use short-form registration statements on Form S-3 for the registration of our securities unless our market capitalization increases substantially, which could impair our ability to raise additional capital as needed.

We May Not Be Able to Realize the Anticipated Benefits of the Aldagen Acquisition

The acquisition of Aldagen, pursuant to which we acquired the ALD-401 RECOVER-Stroke trial and ALDH “Bright Cell” platform, represented a significant investment by the Company. In September 2013, we announced our decision to begin a strategic reorganization of our research and development operations that involved discontinuing clinical trials of ALD-401, which focused on the RECOVER-Stroke trial and one component of the technology present in the ALDH Bright Cell platform. This discontinuation of funding was limited to the above mentioned clinical trial of RECOVER-Stroke, and does not represent a discontinuation of our efforts to develop and commercialize Bright Cell technology. Our efforts to further develop assets acquired from Aldagen, including Bright Cell technologies, will require attention and resources of non-Aldagen Nuo Therapeutics personnel, which could reduce the likelihood of achievement of other corporate goals. We may not successfully manage the various aspects of the Aldagen business, including but not limited to the clinical trial, regulatory, and other functions. Failure to maintain the Aldagen business could lead to a reduction in revenue for the Angel, activAT, and Aurix, products compared to historical levels, generate ill-will among our customer base, and therefore have a material adverse effect on us, our operations or the price of our common stock. The development efforts underway with the remaining Aldagen technology may not be successful.

We Rely on Several Single Source Suppliers and an Interruption in Our Supply Chain Could Have a Material Adverse Effect on Our Business

Nuo Therapeutics outsources the manufacturing of our various products, including component parts, composing the Angel Product Line, to contract manufacturers. While we believe these manufacturers to demonstrate competency, reliability and stability, one or more of them may experience an interruption or inability to provide us with the products needed to satisfy customer demand. During 2014 and 2015, we devoted substantial resources to enhancing and improving the Angel Product Line to meet new and additional regulatory requirements. During the period that we have been implementing the modifications, we were unable to meet our customer's demand for Angel devices. As a result, our sales were lower than expected and in addition, we incurred a charge to earnings of \$600,000 during the year ended December 31, 2014, reflecting our expected costs for refurbishment and design improvements for the units in circulation. Although we believe that we have completed all necessary design modifications to the Angel Products, if further modifications are required, we may experience manufacturing delays and additional costs in the future. Additionally, while most of the components of Aurix are generally readily available on the open market, the reagent, bovine thrombin, is available exclusively through Pfizer. Our single source suppliers may also unilaterally raise the prices charged to use for their services. If a temporary or permanent interruption in the supply of our products were to occur, or the manufacturing costs charged by our suppliers exceed what we can reasonably afford, it would have a material adverse effect on our business. While we are formulating plans to develop redundant capabilities, such capabilities will not take effect for the foreseeable future. While the Company maintains business interruption insurance, such insurance may not be sufficient to cover all losses which may occur as a result of any interruption in supply.

Adverse Conditions in the Global Economy and Disruption of Financial Markets May Significantly Restrict Our Ability to Generate Revenues or Obtain Debt or Equity Financing

The global economy continues to experience volatility and uncertainty. Such conditions could reduce demand for our products which would significantly jeopardize our ability to achieve meaningful market penetration for Aurix and continued sales of Angel and activAT products. These conditions could also affect our potential strategic partners, which, in turn, could make it much more difficult to execute a strategic collaboration, and therefore significantly jeopardize our ability to fully develop and commercialize our products and product candidates. Global credit and capital markets continue to be relatively challenging. We may be unable to obtain capital through issuance of our equity and/or equity-linked securities, which have been a significant source of funding for us throughout our history. If we are unable to secure funding through strategic collaborations, equity investments, or debt financing, we may not be able to achieve profitability, or fund our R&D, which may result in a cessation of our operations.

Business credit and liquidity have tightened in much of the world. Volatility and disruption of financial markets could limit our customers' ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner, or to maintain operations, and result in a decrease in sales volume. General concerns about the fundamental soundness of domestic and international economies may also cause customers to reduce purchases. Changes in governmental banking, monetary and fiscal policies to restore liquidity and increase credit availability may not be effective. Economic conditions and market turbulence may also impact our suppliers' ability to supply sufficient quantities of product components in a timely manner, which could impair our ability to fulfill sales orders. It is difficult to determine the extent of the economic and financial market problems and the many ways in which they may affect our suppliers, customers, investors, and business in general. Continuation or further deterioration of these financial and macroeconomic conditions could significantly harm sales, profitability and results of operations.

Economic downturns or other adverse economic changes (local, regional, or national) could result in losses of portions of principal in our investment portfolio. While our investment policy requires us to invest only in short-term, low risk investments, our principal investment may be eroded, as a significant portion of these investments are in excess of federally mandated insurance.

Our Intellectual Property Assets Are Critical to Our Success

We regard our patents, trademarks, trade secrets and other intellectual property assets as critical to our success. We rely on a combination of patents, trademarks, and trade secret and copyright laws, as well as confidentiality procedures, contractual provisions, and other similar measures, to establish and protect our intellectual property. We attempt to prevent disclosure of our trade secrets by restricting access to sensitive information and requiring employees, consultants, and other persons with access to our sensitive information to sign confidentiality agreements. Despite these efforts, we may not be able to prevent misappropriation of our technology or deter others from developing similar technology in the future. Furthermore, policing the unauthorized use of our intellectual property assets is difficult and expensive. Litigation has been necessary in the past and may be necessary in the future in order to protect our intellectual property assets. Litigation could result in substantial costs and diversion of resources. We can provide no assurance that we will be successful in any litigation matter relating to our intellectual property assets. Continuing litigation or other challenges could result in one or more of our patents being declared invalid. In such a case, any royalty revenues from the affected patents would be adversely affected although we may still be able to continue to develop and market our products. Furthermore, the unauthorized use of our patented technology by otherwise potential customers in our target markets may significantly undermine our ability to generate sales. Any infringement on or challenge to our patents or other misappropriation of our intellectual property assets

could have a material adverse effect on our ability to increase sales of our commercial products and/or continue the development of our pipeline candidates.

Our Products are Subject to Governmental Regulation

Our success is also impacted by factors outside of our control. Our current technology and products are subject to extensive regulation by numerous governmental authorities in the U.S., both federal and state, and in foreign countries by various regulatory agencies. Specifically, our devices and bio-pharmaceutical products are subject to regulation by the FDA and state regulatory agencies. The FDA regulates drugs, medical devices and biologics that move in interstate commerce and requires that such products receive clearance or pre-marketing approval based on evidence of safety and efficacy. The regulations of government health ministries in foreign countries are analogous to those of the FDA in both application and scope. In addition, any change in current regulatory interpretations by, or positions of, state regulatory officials where our products are used could materially and adversely affect our ability to sell products in those states. The FDA will require us to obtain clearance or approval of new devices when used for treating specific wounds or marketed with specific wound-healing claims, or for other products under development.

We believe all our products for sale are legally marketed. As we expand and offer and/or develop additional products in the U.S. and in foreign countries, clearance or approval from the FDA and comparable foreign regulatory authorities prior to introduction of any such products into the market may be required. We provide no assurance that we will be able to obtain all necessary approvals from the FDA or comparable regulatory authorities in foreign countries for these products. Failure to obtain the required approvals would have a material adverse impact on our business and financial condition.

Compliance with FDA and other governmental requirements imposes significant costs and expenses. Further, our failure to comply with these requirements could result in sanctions, limitations on promotional or other business activities, or other adverse effects on our business. Further, recent efforts to control healthcare costs could negatively affect demand for our products and services.

We Must Comply With the Physician Payment Sunshine Act.

We are required to comply with the United States Physician Payment Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies that participate in U.S. federal healthcare programs to report certain payments and items of value given to physicians and teaching hospitals. Manufacturers are required to report this information annually to The Centers for Medicare & Medicaid Services (CMS). The period between August 1, 2013 and December 31, 2013 was the first reporting period for which manufacturers were required to report aggregate payment data to CMS by March 31, 2014. We did not timely file our required report under the Sunshine Act for this first period, and our failure to do so could subject us to certain fines and penalties as set forth below. Manufacturers are required to report aggregate payment data to CMS by the 90th day of each subsequent calendar year. If we fail to accurately and timely report this information in the future, we could suffer severe penalties. We cannot assure you that we will collect and report all data timely and accurately. If we fail to accurately report this information, we could suffer severe penalties. Any applicable manufacturer that fails to timely, accurately, or completely report the information required in accordance with the rules of the Sunshine Act is subject to a civil monetary penalty of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately or completely (up to \$150,000). For "knowing" failures to report, the penalties increase to not less than \$10,000, but not more than \$100,000, for each such failure (up to \$1,000,000). The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization is aggregated separately. Subject to separate aggregate totals, the maximum combined annual total is \$1,150,000.

Clinical Trials May Fail to Demonstrate the Safety or Efficacy of Our Product Candidates

Our product candidates are subject to the risks of failure inherent in the development of biotherapeutic products. The results of early-stage clinical trials do not necessarily predict the results of later-stage clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate desired safety and efficacy traits despite having successfully progressed through initial clinical testing. For example, we discontinued further funding of the ALD-401 development program following results which demonstrated that observed improvements in the primary endpoint of the trial were not clinically or statistically significant. Even if we believe the data collected from clinical trials of our product candidates is promising, this data may not be sufficient to support approval by the U.S. or foreign regulatory agencies. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, the regulatory officials could reach different conclusions in assessing such data, which could delay, limit or prevent regulatory approval. In addition, the U.S. regulatory authorities, or we, may suspend or terminate clinical trials at any time. Any failure or delay in completing clinical trials for product candidates, or in receiving regulatory approval for the sale of any product candidates, has the potential to materially harm our business, and may prevent it from raising necessary, additional financing that may be needed in the future.

A Disruption in Healthcare Provider Networks Could Have an Adverse Effect on Operations and Profitability

Our operations and future profitability are dependent, in large part, upon the ability to contract with healthcare providers on favorable terms. In any particular service area, healthcare providers could refuse to contract with Nuo Therapeutics or take other actions that could result in higher healthcare costs, or create difficulties in meeting our regulatory requirements. In some service areas, certain healthcare providers may have a significant market presence. If healthcare providers refuse to contract with us, use their market position to negotiate unfavorable contracts or place us at a competitive disadvantage, our ability to market services or to be profitable in those service areas could be adversely affected. Provider networks could also be disrupted by the financial insolvency of a large healthcare provider group. Any disruption in provider networks could adversely impact our business, results of operations and financial condition.

Because we have one significant customer, economic difficulties or changes in the purchasing policies or patterns of that customer could have a significant impact on our business and operating results.

One of our customer accounts for a large share of our net sales. In 2014, Arthrex, our largest customer, accounted for approximately 91% of our product sales. The concentration of our business with this customer may expose us to a material adverse effect if this customer were to significantly reduce purchases for any reason, favor competitors or new entrants, or increase their direct competition with us by expanding their own private-label business. Customers make no binding long-term commitments to us regarding purchase volumes. Any customer could reduce its overall purchases of our products, or otherwise seek to materially change the terms of the business relationship at any time. Any such change could significantly harm our business and operating results.

Liquidity problems or bankruptcy of our key customers could have a significant adverse effect on our business, financial condition and results of operations.

Our sales to customers are typically made on credit without collateral. There is a risk that key customers will not pay, or that payment may be delayed, because of bankruptcy, contraction of credit availability to such customers, weak sales or other factors beyond our control, which could increase our exposure to losses from bad debts. In addition, if our key customers were to cease doing business as a result of bankruptcy or significantly reduce their orders from us, it could have a significant adverse effect on our business, financial condition, and results of operations.

We May Be Unable to Attract a Strategic Partner for the Further Development of Certain of Our Product Candidates

Due to our limited resources, we have determined that the best vehicle to ultimately commercialize the various potential indications for ALDHbr, is through strategic partnerships, out-licensing, or other similar arrangements. Even if positive clinical data is eventually achieved in future clinical trials, we may not be able to come to any such agreements, or even have the resources necessary to seek such arrangements. Furthermore, even if such a strategic relationship regarding any of our products or product candidates is reached, development milestones, clinical data, or other such benchmarks may not be achieved. Therefore, these products and product candidates may never proceed toward commercialization or drive cash infusions for us, and we may ultimately not be able to monetize the patents, existing clinical data, and other intellectual property.

The Successful Continued Commercialization of Our Aurix System and Angel and of Any Future Product Candidates Will Depend on Obtaining Reimbursement from Third-party Payors

In the U.S., the market for any pharmaceutical or biologic product is affected by the availability of reimbursement from third party payors, such as government health administration authorities, private health insurers, health maintenance organizations and pharmacy benefit management companies. If we cannot demonstrate a favorable cost-benefit relationship, we may have difficulty obtaining adequate reimbursement for our products from these payors. Third-party payors may also deny coverage or offer inadequate levels of reimbursement for any of our products if they determine that the product is experimental, unnecessary or inappropriate. Should we seek to expand our commercialization internationally, we would be subject to the international regulations, where the pricing of prescription pharmaceutical products and services and the level of government reimbursement may be subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct one or more clinical trials that compare the cost effectiveness of our product candidates or products to other available therapies. Conducting one or more of these clinical trials would be expensive and result in delays in commercialization of our products.

Managing and reducing healthcare costs has become a major priority of federal and state governments in the U.S. As a result of healthcare reform efforts, we might become subject to future regulations or other cost-control initiatives that materially restrict the price we can receive for our products. Third-party payors may also limit access and reimbursement for newly approved healthcare products generally or limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

Our Efforts to Secure Unrestricted Medicare Reimbursement in a Timely and Efficient Manner May Not be Successful

The Aurix™ system is marketed to healthcare providers. Some of these providers, in turn, seek reimbursement from third-party payors such as Medicare, Medicaid, and other private insurers. Under such healthcare systems, reimbursement is often a determining factor in predicting a product's success, with some physicians and patients strongly favoring only those products for which they will be reimbursed. In light of the foregoing and other related factors, we may not ultimately be successful with our reimbursement strategy, including, without limitation, obtaining additional necessary CMS or other regulatory approvals. For example, CMS may not determine that the evidence collected under CED is sufficient to provide unrestricted Medicare coverage for the Aurix™ system and autologous PRP, which, in turn, could have a material adverse effect on our financial state and business operations. If it is later determined that a new randomized, controlled trial is necessary, it could cost several millions of dollars and take multiple years to complete. We would almost certainly need to obtain additional, outside financing to fund such a trial. In any case, we may never be successful in securing unrestricted Medicare coverage for our products.

Our Sales and Marketing Strategy for the Aurix System May Not Succeed

In October 2014, we relaunched our AutoloGel chronic wound care system under the Aurix™ brand, as a part of our marketing plan for the commercialization of Aurix™ in the U.S. chronic wound care market. Since January 2009, the sales and marketing strategy for this system was focused on intensive clinician to clinician interaction, with both prospective and existing customers, and the scientific explanation of the system's mechanism of action. However, the primary goal of this effort was to help secure the additional data necessary to obtain Medicare coverage. Following the 2012 determination by the CMS which, in essence, permitted coverage of Aurix™ under its CED program, we have been positioning the Company to expand its sales efforts to address the Medicare beneficiary population. This will require selling to wound care clinics, individual physician practices, and other venues that have traditionally not been available to us due to the previously standing non-coverage determination by CMS. The Company's efforts in this new sales channel may not be successful, and even if successful, they may not yield sufficient sales and profits to realize the Company's goals and conform to its plans. If and to the extent CMS makes significant changes to its previously issued approval determinations, or we are unable to reverse the October 2014 protocol denial determination, or the currently approved protocols are not enrolled in a timely manner, our sales and marketing strategy may be adversely affected.

Our Efforts to Secure Commercial Partners May Not Be Successful

From time to time, we engage in discussions with larger companies regarding potential strategic partnerships involving the broad commercialization of Aurix™. The resources and expertise of such a partner would greatly facilitate the capture of market share within the wound care market, but would require that the economic benefits of such a broad penetration would be shared with said partner. We may not be successful in securing such a partner. Furthermore, even if a partner is secured, the partnership may not attain the market penetration contemplated, and the profits ultimately realized by Nuo Therapeutics, if any, may not be sufficient to allow us to execute our business strategy.

We May Use Third-party Collaborators and Service Providers to Help us Support, Develop or Commercialize Our Product Candidates, and Our Ability to Commercialize Such Candidates May be Impaired or Delayed if such Collaborations or Engagements are Unsuccessful

We do presently and may in the future selectively pursue strategic collaborations or engagements for, among other purposes, development, data collection, analysis, and/or commercialization of our product candidates, domestically or otherwise. There can be no assurance as to our ability to utilize the data from such engagements to their potential. Nor can there be any assurance, in general, that we will be able to identify future suitable collaborators or negotiate collaboration agreements on terms that are acceptable to us or at all. In any current or future third-party collaborations, we are and would be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation and engagement. For a variety of reasons outside of our control, our collaborators or third-party providers may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also result in product development delays, decreased revenues and litigation expenses.

The Success of Our Products Is Dependent on Acceptance by the Medical Community

The commercial success of our products and processes will depend upon the medical community and patients accepting the therapies as safe and effective. The willingness of the medical community to accept or evaluate our products and processes may be impacted by our ability to cause such information to be included in peer-reviewed literature. We may not have the resources necessary to cause such information to be included in peer-reviewed literature. If the medical community and patients do not ultimately accept the therapies as safe and effective, or we are unable to raise awareness of our products and processes, our ability to sell the products may be materially and adversely affected, and the results of our operations may be adversely effected.

We May Be Unable to Attract and Retain Key Personnel

Our future success depends on the ability to attract, retain and motivate highly skilled management, including sales representatives. We have retained a team of highly qualified officers and consultants, but may not be able to successfully retain all of them, or be successful in recruiting additional personnel as needed. Our inability to do so will materially and adversely affect the business prospects, operating results and financial condition of the Company. Our ability to maintain and provide additional services to our customers depends upon our ability to hire and retain business development and scientific and technical personnel with the skills necessary to keep pace with continuing changes in regenerative biological therapy technologies. Competition for such personnel is intense; we compete with pharmaceutical, biotechnology and healthcare companies with greater access to resources. Our inability to hire additional qualified personnel may lead to higher recruiting, relocation and compensation costs for such personnel. These increased costs may reduce our profit margins or make hiring new key personnel impractical.

Legislative and Administrative Action May Have an Adverse Effect on Our Company

Political, economic and regulatory influences are subjecting the health care industry in the U.S. to fundamental change. We cannot predict what other legislation relating to our business or to the health care industry may be enacted, including legislation relating to third-party reimbursement, or what effect such legislation may have on our business, prospects, operating results and financial condition. We expect federal and state legislators to continue to review and assess alternative health care delivery and payment systems, and possibly adopt legislation affecting further changes in the health care delivery system. Such laws may contain provisions that may change the operating environment for hospitals and managed care organizations. Health care industry participants may react to such legislation by curtailing or deferring expenditures and initiatives, including those relating to our products. Future legislation could result in modifications to the existing public and private health care insurance systems that would have a material adverse effect on the reimbursement policies discussed above. With growing pressures on government budgets due to the current economic downturn, government efforts to contain or reduce health care spending are likely to gain increasing emphasis. Several members of the current presidential administration and Congress are espousing support for cost-containment measures that could have significant implications for healthcare therapies, including our current and future products. If enacted and implemented, such measures could result in decreased revenue from our products and decrease potential returns from our research and development initiatives. Furthermore, we may not be able to successfully neutralize any lobbying efforts against any initiatives we may have with governmental agencies.

We Could Be Affected by Malpractice or Product Liability Claims

Providing medical care entails an inherent risk of professional malpractice and other claims. We do not control or direct the practice of medicine by physicians or health care providers who use our products and do not assume responsibility for compliance with regulatory and other requirements directly applicable to physicians. There is no assurance that claims, suits or complaints relating to the use of our products, and treatment administered by physicians, will not be asserted against us in the future. The production, marketing and sale, and use of our products entails risks that product liability claims will be asserted against us. These risks cannot be eliminated, and we could be held liable for any damages that result from adverse reactions or infectious disease transmission. Such liability could materially and adversely affect our business, prospects, operating results and financial condition. We currently maintain professional and product liability insurance coverage, but the coverage limits of this insurance may not be adequate to protect against all potential claims. We may not be able to obtain or maintain professional and product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities.

Our Products Have Existing Competition in the Marketplace

In the market for biotechnology products, we face competition from pharmaceutical companies, biopharmaceutical companies, medical device companies, and other competitors. Other companies have developed or are developing products that may be in direct competition with our current product line. Biotechnology development projects are characterized by intense competition. Thus, we may not be the first to the market with any newly developed products and we may not successfully be able to market these products. If we are not able to participate and compete in the regenerative biological therapy market, our financial condition will be materially and adversely affected. We may not be able to compete effectively against such companies in the future. Many of these companies have substantially greater capital resources, larger marketing staffs and more experience in commercializing products than we do. Recently developed technologies, or technologies that may be developed in the future, may be the basis for developments that will compete with our products.

Development of Our Aldagen Product Candidates is Subject to Uncertainty Because Each is Derived from Human Bone Marrow, a Source Material That is Inherently Variable

The number of ALDHbr "Bright Cell" cells and the composition of the ALDHbr cell population from bone-marrow vary from patient to patient. Such variability in composition could adversely affect our ability to manufacture our Aldagen product candidates derived from a patient's bone-marrow or to establish and meet acceptable specifications for release of the product candidate for treatment of a particular patient. As a consequence, the development and regulatory approval process for these product candidates could be delayed or may never be completed.

If We Determine That Our Intangible Assets Have Become Impaired in the Future, Our Total Assets and Earnings Could Be Adversely Affected.

As of December 31, 2014, we had recorded goodwill of \$1.1 million and intangible assets, net of \$28.7 million, primarily as a result of the February 2012 acquisition of Aldagen. In June 2014, following the discontinuance of our ALD-401 trials, we concluded that the initial fair value of the Aldagen related trademarks of approximately \$1.8 million, and IPR&D of approximately \$3.7 million, was impaired. As a result an impairment charge of approximately \$4.7 million was taken in the three months period ending June 30, 2014. Goodwill represents the purchase price of acquisitions in excess of the amounts assigned to acquired tangible or intangible assets and assumed liabilities. Goodwill and indefinite lived intangible assets are not amortized but rather are evaluated for impairment annually or more frequently, if indicators of impairment exist. Finite lived intangible assets are evaluated for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If the impairment evaluations for goodwill and intangible assets indicate the carrying amount exceeds the estimated fair value, an impairment loss is recognized in an amount equal to that excess.

We Have Only Limited Experience Manufacturing Our Aldagen Product Candidates. We May Not Be Able to Manufacture Our Aldagen Product Candidates in Compliance With Evolving Regulatory Standards or in Quantities Sufficient for Commercial Sale

Components of therapeutic products approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP as required by the FDA. Manufacturers of cell-based product candidates, such as our Aldagen product candidates, also must comply with the FDA's current good tissue practices, or cGTP. In addition, we may be required to modify our manufacturing process from time-to-time for our product candidates in response to FDA requests. Manufacture of live cellular-based products is complex and subjects us to significant regulatory burdens that may change over time. We may encounter difficulties in the production of our Aldagen product candidates due to our limited manufacturing capabilities. We have only limited manufacturing experience with our Aldagen product candidates, and we currently do not have sufficient manufacturing capacity to support commercialization of any of our Aldagen product candidates. These difficulties could reduce sales of our Aldagen products, if they are approved for marketing, increase our costs or cause production delays, any of which could damage our reputation and hurt our profitability.

If we successfully obtain marketing approval for any Aldagen product candidates, we may not be able to efficiently produce sufficient quantities of these products to meet potential commercial demand. We expect that we would need to significantly expand our manufacturing capabilities to meet potential demand for these products. Such expansion would require additional regulatory approvals. We may also encounter difficulties in the commercial-scale manufacture of all of our product candidates. We are currently developing new processes and are in discussions with other companies to develop new instruments to improve our manufacturing efficiency. Improving the speed and efficiency of our manufacturing process and the cell sorters and other instruments we use is a key element of our business plan. However, we may not be able to develop process enhancements on a timely basis, on commercially reasonable terms, or at all. If we fail to develop these improvements, we could face significantly higher capital expenditures than we anticipate, increased facility and personnel costs and other increased operating expenses. We may need to demonstrate that our product candidates manufactured using any new processes or instruments are comparable to our product candidates used in clinical trials. Depending on the type and degree of differences, we may be required to conduct additional studies or clinical trials to demonstrate comparability.

In addition, some changes in our manufacturing processes or procedures, including a change in the location where a product candidate is manufactured, generally require prior FDA or foreign regulatory authority review and approval for determining our compliance with cGMP and cGTP. We may need to conduct additional preclinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of Aldagen our product candidates.

We May Use Third-party Collaborators to Help us Develop or Commercialize Our Product Candidates, and Our Ability to Commercialize Such Candidates May be Impaired or Delayed if Collaborations are Unsuccessful

We may in the future selectively pursue strategic collaborations for the development and commercialization of our product candidates and for the international development and commercialization of our product candidates. For example, we may not be able to commercialize ALD-201 successfully without entering into an arrangement with a third party to provide an approved method of administration. We may not be able to identify suitable collaborators or negotiate collaboration agreements on terms that are acceptable to us, or at all. In any future third-party collaboration, we would be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also result in product development delays, decreased revenues and litigation expenses.

Ethical and Other Concerns Surrounding the Use of Stem Cell-based Therapy May Negatively Affect Public Perception of Us or Our Product Candidates, thereby Reducing Potential Demand for Our Products

The commercial success of our product candidates, which are based on adult stem cells, will depend in part on general public acceptance of the use of stem cell-based therapy for the prevention or treatment of human diseases. The use of embryonic stem cells and fetal tissue for research and stem cell therapy has been the subject of substantial national and international debate regarding related ethical, legal and social issues. We do not use embryonic stem cells or fetal tissue in any of our product candidates, but the public may not be able to, or may fail to, differentiate our use of adult stem cells from the use by others of embryonic stem cells or fetal tissue. This could result in a negative perception of our company or our product candidates. Some people have raised ethical concerns about the use of donated human tissue in a commercial setting, which could also negatively affect the perception of our product candidates and inhibit their commercialization in a successful manner.

If Our Patent Position Does Not Adequately Protect Our Product Candidates or Any Future Products, Others Could Compete Against Us More Directly, Which Would Harm Our Business

Our success depends, in large part, on our ability to obtain and maintain patent protection for our product candidates. Issued patents may be challenged by third parties, resulting in patents being deemed invalid, unenforceable or narrowed in scope, or a third party may circumvent any such issued patents. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions and has been the subject of much litigation and recent court decisions introduce uncertainty in the strength of patents owned by biotechnology companies. The legal systems of some foreign countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Therefore, any patents that we own or license may not provide sufficient protection against competitors.

The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, the two issued U.S. patents relating to our product candidates are limited to a particular chemistry in the manufacturing process. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different chemistry, these patents will not prevent others from directly competing with us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our product candidates, thereby reducing any advantages of the patent. For instance, one of our patents relating to our technology will expire in 2019. To the extent our product candidates based on that technology are not commercialized significantly ahead of this date, or to the extent we have no other patent protection on such product candidates, those product candidates would not be protected by patents beyond 2019 and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the Federal Food, Drug and Cosmetic Act, which may provide less protection of our competitive position. Similar considerations apply in any other country where we are prosecuting patents, have been issued patents, or have licensed patents or patent applications relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the U.S.

If We Are Unable to Protect the Confidentiality of Our Proprietary Information and Know-how, Our Competitive Position Would be Impaired

A significant amount of our technology, especially regarding manufacturing processes, is unpatented and is maintained by us as trade secrets. The background technologies used in the development of our product candidates are known in the scientific community, and it is possible to duplicate the methods we use to create our product candidates. In an effort to protect these trade secrets, we require our employees, consultants and contractors to execute confidentiality agreements with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. The disclosure of our trade secrets would impair our competitive position.

If We Infringe, or Are Alleged to Infringe, Intellectual Property Rights of Third Parties, Our Business Could be Harmed

Our research, development and commercialization activities, including any product candidates resulting from these activities, may infringe, or be claimed to infringe, patents or other proprietary rights owned by third parties, and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages.

Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We have not conducted an exhaustive search or analysis of third-party patent rights to determine whether our research, development or commercialization activities, including any product candidates resulting from these activities, may infringe or be alleged to infringe any third-party patent rights. As a result of intellectual property infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the licensee would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also affect our potential collaborators to the extent we have any collaborations then in place, which would also affect the success of the collaboration and therefore us. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U. S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our product candidates and technology.

Uncertainties Resulting from the Initiation and Continuation of Patent Litigation or Other Proceedings Could Have a Material Adverse Effect on Our Ability to Compete in the Marketplace

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including the following:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs that we expect to be promising;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- we may be subject to a more complex regulatory process, since stem cell-based therapies are relatively new and regulatory agencies have less experience with them than with traditional pharmaceutical products;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to halt or terminate the trials.

Any Product for Which We Obtain Marketing Approval Will be Subject to Extensive Ongoing Regulatory Requirements, and We May Be Subject to Penalties if We Fail to Comply with Regulatory Requirements or if We Experience Unanticipated Problems with Our Products, When and if Any of Them Are Approved

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP and cGTP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements relating to product labeling, advertising and promotion, and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to additional limitations on the indicated uses for which the product may be marketed or to other conditions of approval. In addition, approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Discovery after approval of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on such products' manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

Failure to Obtain Regulatory Approval in International Jurisdictions Would Prevent Us from Marketing Products Abroad

We may in the future seek to market some of our product candidates outside the U.S. In order to market our product candidates in the European Union and many other jurisdictions, we must submit clinical data concerning our product candidates and obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval from foreign regulators may be longer than the time required to obtain FDA approval. The regulatory approval process outside the U.S. may include all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product candidate be approved for reimbursement before it can be approved for sale in that country. In some cases this may include approval of the price we intend to charge for our product, if approved. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA, but a failure or delay in obtaining regulatory approval in one country may negatively affect the regulatory process in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize any products in any market and therefore may not be able to generate sufficient revenues to support our business.

Our Business Involves the Use of Hazardous Materials That Could Expose Us to Environmental and Other Liability

Our manufacturing facility located in Durham, North Carolina (currently under sublease) is subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our R&D activities. In the U.S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. In the European Union, these laws include RoHS. Accidental contamination or injury to our employees and third parties from hazardous materials may occur. If our products do not comply with the European substance restrictions, we could become subject to fines, civil or criminal sanctions, and contract damage claims. In addition, we could be prohibited from shipping non-compliant products into the European Union, and be required to recall and replace any products already shipped, if such products were found to be non-compliant which would disrupt our ability to ship products and result in reduced revenue. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other than limited clean-up expense coverage for environmental contamination due to an otherwise insured peril, such as fire.

The Sale of Our Common Stock to Lincoln Park May Cause Substantial Dilution to Our Existing Stockholders and the Sale of the Shares of Common Stock Acquired by Lincoln Park Could Cause the Price of Our Common Stock to Decline

In February 2013, we entered into a purchase agreement with Lincoln Park whereby we could, but are not required to, sell shares of our common stock to Lincoln Park over 30 month period up to a maximum aggregate amount of \$15 million. The number of shares ultimately offered for sale by Lincoln Park is dependent upon the number of shares we elect to sell to Lincoln Park under the purchase agreement and the availability of the resale registration statement. Depending upon market liquidity at the time, sales of shares of our common stock by Lincoln Park may cause the trading price of our common stock to decline. After it has acquired shares under the purchase agreement, Lincoln Park may sell all, some or none of those shares. Sales to Lincoln Park by us pursuant to the purchase agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Lincoln Park, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park and the purchase agreement may be terminated by us at any time at our discretion without any cost to us.

Volatility of Our Stock Price Could Adversely Affect Current and Future Stockholders

The market price of our common stock has been volatile, and fluctuates widely in price in response to various factors which are beyond our control. The price of our common stock is not necessarily indicative of our operating performance or long-term business prospects. In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock. Factors that could cause the market price of our common stock to fluctuate substantially include, among others:

- our ability or inability to execute our business plan;
- the dilutive effect or perceived dilutive effect of additional equity financings;
- investor perception of our company and of the industry;
- the success of competitive products or technologies;
- regulatory developments in the U.S. or overseas;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel; or

- general economic, political and market conditions.

The stock market in general has recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility could be worse if the trading volume of our common stock is low.

We May Likely Issue Additional Equity or Debt Securities Which May Materially and Adversely Affect the Price of Our Common Stock

Sales of substantial amounts of shares of our common stock in the public market, or the perception that those sales may occur, could cause the market price of our common stock to decline. We have used, and will likely continue to use, our common stock or securities convertible into or exchangeable for common stock to fund working capital needs or to acquire technology, product rights or businesses, or for other purposes. If additional equity and/or equity-linked securities are issued, particularly during times when our common stock is trading at relatively low price levels, the price of our common stock may be materially and adversely affected.

The Exercise of Warrants or Certain Conversion Features Issued to Deerfield in Connection with the Facility Agreement May Cause Substantial Dilution to Our Existing Stockholders,

We issued Deerfield warrants to purchase a total of 92,615,385 shares of our common stock in connection with the Facility Agreement. Warrants to purchase 25,115,385 shares were issued to Deerfield on March 31, 2014, and warrants to purchase 67,500,000 shares of common stock were issued to Deerfield on June 25, 2014. Each warrant has an expiration date of seven years from the applicable date of issuance, is initially exercisable at \$0.52 per share, and the number of shares issuable upon their exercise is subject to certain adjustments. Deerfield also has the right to convert the principal amount of the Facility Agreement into shares of our common stock at a per share price equal to \$0.52. The maximum number of shares of our common stock that can be issued pursuant to the conversion of the Deerfield facility is 67,307,692 shares; the maximum number of shares of our common stock that can be issued pursuant to the terms of the Deerfield warrants is 92,615,385 shares. The exercise of these warrants or conversion rights may cause substantial dilution to our existing stockholders.

There is a Limited Public Trading Market for Our Common Stock

The average daily trading volume in our common stock has historically been relatively low. If low trading volume is persistent, it could be difficult to sell a significant number of shares of common stock at any particular time at the market prices prevailing immediately before such shares are offered. Shareholders may be required to hold shares of our common stock for an indefinite period of time. In addition, sales of substantial amounts of common stock could lower the prevailing market price of our common stock. This would limit or perhaps prevent our ability to raise capital through the sale of securities. Additionally, we have significant numbers of outstanding warrants and options that, if exercised and sold, could put additional downward pressure on the common stock price. In addition, in recent years the stock market in general, and the market for life sciences companies in particular, have experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and it may adversely affect the price of our common stock. These broad market fluctuations may reduce the demand for our stock and therefore adversely affect the price of our securities, regardless of operating performance.

We are Subject to Anti-Takeover Provisions and Laws

Provisions in our restated certificate of incorporation and restated bylaws and applicable provisions of the Delaware General Corporation Law may make it more difficult for a third party to acquire control of us without the approval of our Board of Directors. These provisions may make it more difficult or expensive for a third party to acquire a majority of our outstanding voting common stock or delay, prevent or deter a merger, acquisition, tender offer or proxy contest, which may negatively affect our common stock price.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our principal executive offices are located at 207A Perry Parkway, Suite 1, Gaithersburg, MD 20877 and our warehouse facility is located at 209 Perry Parkway, Suite 7, Gaithersburg, MD 20877. These facilities are comprised of approximately 12,000 square feet. These facilities fall under two leases with monthly rent, including our share of certain annual operating costs and taxes, at approximately \$13,000 and \$4000 per month with the leases expiring September 2019. In addition, we also lease a 2,076 square foot facility in Nashville, Tennessee which is being utilized as a commercial operations office. The lease is approximately \$4,000 per month excluding our shares of annual operating expenses and expires April 30, 2018. We also lease a 16,300 square foot facility in Durham, North Carolina which we initially used to conduct research and development primarily focused on our ALD-401 program. The lease is approximately \$20,000 per month, including our share of certain annual operating costs and taxes, and expires December 31, 2018. Following the discontinuation of funding for our ALD-401 program in May 2014, we have subleased the facility. The sublease rent is approximately \$13,000 per month and expires December 31, 2018. The Company does not own any real property and does not intend to invest in any real property in the foreseeable future.

ITEM 3. Legal Proceedings

We are not party to, nor is our property the subject of, any material legal proceedings.

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 shares of common stock are quoted for trading on the OTC Markets Group OTCQX marketplace (the "OTCQX") under the symbol "NUOT." Between January 26, 2011 and November 13, 2014, the Company's common stock was quoted under the trading symbol "CMXI."

The following table sets forth, for the periods indicated, the high and low bid information for our common stock as determined from quotations on the OTCQX. The quotations reflect inter-dealer prices, without retail markup, markdown, or commissions, and may not represent actual transactions.

Quarter ended	High	Low
December 31, 2014	\$ 0.35	\$ 0.31
September 30, 2014	\$ 0.40	\$ 0.39
June 30, 2014	\$ 0.41	\$ 0.39
March 31, 2014	\$ 0.54	\$ 0.50
December 31, 2013	\$ 0.68	\$ 0.33
September 30, 2013	\$ 0.50	\$ 0.37
June 30, 2013	\$ 0.53	\$ 0.43
March 31, 2013	\$ 0.77	\$ 0.48

On March 20, 2015, the closing sales price of our common stock as reported on the OTC Markets Group OTCQX marketplace was \$0.24 per share.

Holders

There were approximately 468 holders of record of our common stock as of March 20, 2015.

Dividends

We have not paid or declared cash distributions or dividends on our common stock in 2014 or 2013 and we do not intend to pay cash dividends on our common stock in the foreseeable future. We currently intend to retain all earnings, if and when generated, for reinvestment in our business.

Penny Stock

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Our stock is currently a "penny stock." Penny stocks are generally equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document prepared by the SEC, which: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation of such duties or other requirements of securities' laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and significance of the spread between the bid and ask price; (d) contains a toll-free telephone number for inquiries on disciplinary actions; (e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and (f) contains such other information and is in such form as the SEC shall require by rule or regulation. The broker-dealer also must provide to the customer, prior to effecting any transaction in a penny stock, (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our stock.

Issuer Purchases of Equity Securities

The Company did not make any stock repurchases during the last quarter of 2014

Recent Sales of Unregistered Securities

Except as previously reported in the Company's Current Reports on Form 8-K, Quarterly Reports on Form 10-Q and elsewhere in this filing, there have been no unregistered sales of securities in 2014.

ITEM 6. Selected Financial Data

Not Applicable.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The discussion in this section regarding the Company's business and operations includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements consist of any statement other than a recitation of historical fact and can be identified by the use of forward-looking terminology such as "may," "expect," "anticipate," "estimate," or "continue," or the negative thereof or other variations thereof or comparable terminology. You are cautioned that all forward-looking statements are speculative, and there are certain risks and uncertainties that could cause actual events or results to differ from those referred to in such forward-looking statements. Actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the "Risk Factors" section and elsewhere in this Annual Report. The Company assumes no obligation to update any such forward-looking statements. The following should be read in conjunction with the audited financial statements and the notes thereto included elsewhere herein. Certain numbers in this section have been rounded for ease of analysis.

Corporate Overview

Nuo Therapeutics is a regenerative therapies company developing and marketing products within the U.S. and internationally. We commercialize innovative cell-based technologies that harness the regenerative capacity of the human body to trigger natural healing. The use of autologous (from self) biological therapies for tissue repair and regeneration is part of a transformative clinical strategy designed to improve long term recovery in complex chronic conditions with significant unmet medical needs.

Our current commercial offerings consist of point of care technologies for the safe and efficient separation of autologous blood and bone marrow to produce platelet based therapies or cell concentrates. Today, we have two distinct PRP devices, the Aurix System for wound care and the Angel cPRP system for orthopedics markets. Our product sales are predominantly (approximately 73%) in the U.S., where we sell our products through direct sales representatives and our Arthrex Distributor and License Agreement. Growth drivers in the U.S. include Medicare coverage for the treatment of chronic wounds under a NCD when registry data is collected under CED, and a worldwide distribution and licensing agreement that allows our partner to promote the Angel System for all uses other than wound care.

The Aurix™ System

The Aurix System is a point of care device for the production of a platelet based bioactive wound treatment derived from a small sample of the patient's own blood. Aurix is cleared by the FDA for use on exuding wounds and is currently marketed in the chronic wound market. Chronic wounds account for an estimated \$6 billion to \$15 billion annually in U.S. health care costs. The most significant growth driver for Aurix is the 2012 NCD from the CMS which reversed a twenty year old non-coverage decision for autologous blood products used in wound care. Using the patient's own platelets as a therapeutic agent, Aurix harnesses the body's natural healing processes to deliver growth factors, chemokines and cytokines known to promote angiogenesis and to regulate cell growth and the formation of new tissue. Once applied to the prepared wound bed, the biologically active platelet gel can restore the balance in the wound environment to transform a non-healing wound to a wound that heals naturally. There have been nine peer-reviewed scientific and clinical publications demonstrating the effectiveness of Aurix in the management of chronic wounds since the device and gel was cleared by the FDA in 2007.

The Company will continue to pursue potential partnerships and commercial agreements for the product with interested parties.

Other Developments

In September 2009, we entered into a license and distribution agreement with Millennia Holdings, Inc. ("Millennia") for the Company's Aurix System in Japan. Since then, Millennia has been collecting and publishing clinical data for regulatory purposes and expanding the utilization of Aurix throughout their network. The diabetic population in Japan is estimated to be approximately seven million adults. Millennia has assisted the Company in securing a partner to address widespread distribution in Japan.

In January 2015 we granted to Rohto a royalty bearing, nontransferable, exclusive license, with limited right to sublicense, to use certain of the Company's intellectual property for the development, import, use, manufacturing, marketing, sale and distribution for all wound care and topical dermatology applications of the Aurix system and related intellectual property and know-how in human and veterinary medicine in Japan in exchange for an upfront payment from Rohto of \$3.0 million (which is reduced by the \$1.5 million payment to Millennia Holdings, as set forth below). The agreement also contemplates additional royalty payments based on the net sales of Aurix in Japan and an additional future cash payment in the event specific milestones are met.

In connection with and effective as of the entering into the Rohto Agreement, we executed Amendment No. 5 to the Licensing and Distribution Agreement with Millennia dated September 10, 2009, as subsequently amended to terminate the Millennia Agreement and to allow us to transfer the exclusivity rights from Millennia to Rohto. In connection with this amendment we paid a one-time, non-refundable fee of \$1.5 million to Millennia upon our receipt of the \$3.0 million upfront payment from Rohto and may be required to pay certain future royalty payments to Millennia based upon net sales in Japan. Millennia has been instrumental in establishing the advanced wound care market in Japan, and will continue to work with Rohto to develop the market for Aurix. Further, Rohto has assumed all responsibility for securing the MA from Japan's MHLW, while we will provide relevant product information, as well as clinical and other data to support Rohto's MA application.

Angel Product Line

The Angel cPRP System, acquired from Sorin in April 2010, is designed for single patient use at the point of care, and provides a simple yet flexible means for producing quality PRP and PPP from whole blood or bone marrow. The Angel cPRP System is a multi-functional cell separation device which produces cPRP for use in the operating room and clinic and is used in a range of orthopedic and cardiovascular indications. The Angel System is a point of care device for the production of a concentrated, aseptic platelet-based bioactive therapy derived from a small sample of the patient's own blood.

In August 2013, we entered into a Distributor and License Agreement with Arthrex. Under the terms of this agreement, Arthrex obtained the exclusive rights to sell, distribute, and service our Angel Concentrated Platelet System and ActivAT throughout the world for all uses other than chronic wound care. We granted Arthrex a limited license to use our intellectual property as part of enabling Arthrex to sell these products. Arthrex purchases these products from us to distribute and service. Arthrex pays us a certain royalty rate based upon volume of the products sold. The exclusive nature of Arthrex's rights to sell, distribute and service the products is subject to certain existing supply and distribution agreements such that Arthrex may instruct us to terminate or not renew any of such agreements. In addition, Arthrex's rights to sell, distribute and service the products is not exclusive in the non-surgical dermal and non-surgical aesthetics markets.

ALDH br, or Bright Cell, Technology and Development Pipeline

We acquired the ALDHbr "Bright Cell" technology as part of our acquisition of Aldagen in February 2012. The Bright Cell technology is a novel approach to cell-based regenerative medicine with potential clinical indications in large markets with significant unmet medical needs, such as peripheral arterial disease and ischemic stroke. The Bright Cell technology is unique in that it utilizes an intracellular enzyme marker to facilitate fractionation of essential regenerative cells from a patient's bone marrow. This core technology was originally licensed by Aldagen from Duke and JHU. The proprietary bone-marrow fractionation process identifies and isolates active stem and progenitor cells expressing high levels of the enzyme aldehyde dehydrogenase, or ALDH, which is a key enzyme involved in the regulation of gene activities associated with cell proliferation and differentiation. These autologous, selected biologically instructive cells have the potential to promote the repair and regeneration of multiple types of cells and tissues, including the growth of new blood vessels, or angiogenesis, which is critical to the generation of healthy tissue.

Reorganization of Research and Development Operations related to ALD-401

In September 2013, we announced our decision to begin a strategic reorganization of our research and development operations that involved discontinuing clinical trials of ALD-401, which focused on the RECOVER-Stroke trial and one component of the technology present in the ALDH Bright Cell platform. This discontinuation was limited to the above mentioned clinical trial of RECOVER-Stroke, and does not represent our discontinuation of efforts to develop and commercialize Bright Cell technology. Following the January 2014 completion of the trial enrollment in the RECOVER-Stroke trial, in May 2014 we announced preliminary efficacy and safety results of our RECOVER-Stroke Phase 2 clinical trial in patients with neurological damage arising from ischemic stroke and treated with ALD-401. Observed improvements in the primary endpoint (mean modified Rankin Score or mRS) of the trial were not clinically or statistically significant. In light of this outcome, we discontinued further funding of the ALD-401 development program, and in connection therewith, closed our R&D facility in Durham, NC, which supported the development of ALD-401. This decision to close down the facility was in line with the overall realignment of our commercial operations to focus on the wound care market. Following the foregoing actions and events, we performed an assessment of the Aldagen tradename, IPR&D, and goodwill and concluded that the fair value of the Aldagen trade name and its IPR&D was impaired.

Continued Development of Bright Cell Technology

Notwithstanding the discontinuation of further funding of the RECOVER-Stroke clinical trials, we will continue to develop the Bright Cell technology platform for other uses, and will conduct a Phase 1/2 clinical trial in critical limb ischemia (PACE), that is being funded by the National Institutes of Health, and a Phase 1 clinical trial in grade IV malignant glioma following surgery, that is funded by Duke University.

Comparison of Years Ended December 31, 2014 and 2013 (rounded to nearest thousand)

Revenue and Gross Profit

Revenues decreased \$3,810,000 (33%) to \$7,762,000, comparing the year ended December 31, 2014 to the previous year. This was primarily due to a decrease in product sales of \$4,649,000 and service revenue of \$201,000, offset by an increase in royalties of \$807,000 and license fee revenue of \$235,000.

Overall gross profit decreased \$2,127,000 (68%) to \$991,000 while overall gross margin decreased to 13% from 27%, comparing the year ended December 31, 2014 to the previous year. Angel disposable products, under the Arthrex Agreement, were sold at a lower average selling price in 2014 as compared to the prior year. In addition we recognized increased costs related to actual and expected Angel centrifuge refurbishment costs and an inventory reserve established for excess and obsolete inventory. This was partially offset by an increase in gross profit and margin from Angel related license fees and royalty revenue.

The following table presents the profitability of sales:

	Twelve Months Ended December 31,							
	Aurix		Angel		Bright Cell		Total	
	2014	2013	2014	2013	2014	2013	2014	2013
Product sales	\$ 495,000	\$ 567,000	\$ 5,354,000	\$ 9,927,000	\$ -	\$ 4,000	\$ 5,849,000	\$ 10,498,000
License Fees	-	-	402,000	168,000	-	-	402,000	168,000
Royalties	-	-	1,264,000	454,000	247,000	250,000	1,511,000	704,000
Other revenue	-	-	-	201,000	-	-	-	201,000
Total revenues	495,000	567,000	7,020,000	10,750,000	247,000	254,000	7,762,000	11,571,000
Product cost of sales	418,000	329,000	6,176,000	8,035,000	-	-	6,594,000	8,364,000
License fees cost of sales	-	-	-	-	-	-	-	-
Royalty cost of sales	-	-	157,000	69,000	20,000	20,000	177,000	89,000
Other revenue cost of sales	-	-	-	-	-	-	-	-
Total cost of revenues	418,000	329,000	6,333,000	8,104,000	20,000	20,000	6,771,000	8,453,000
Gross profit/(Loss)	77,000	238,000	687,000	2,646,000	227,000	234,000	991,000	3,118,000
Gross margin	16%	42%	10%	25%	92%	92%	13%	27%

AurixTM product sales decreased \$72,000 while gross profit decreased \$161,000 comparing the year ended December 31, 2014 to the previous year. The decrease in gross profit and gross margin was primarily due to cost of sales related to royalty expense amortization that began March 2013, higher depreciation expense, and an increase in inventory obsolescence. The royalty expense

is related to the release of the Worden security interest in Aurix[™] patents to the Company.

Angel product sales decreased \$4,573,000 while gross profit decreased \$2,714,000 comparing the year ended December 31, 2014 to the previous year. Product sales decreased partially as a result of the one-time, zero margin non-recurring sale to Arthrex in 2013 of \$1,294,000 for existing, placed Angel centrifuges made pursuant to the terms and provisions of the Arthrex Agreement. Angel sales volume decreased and, under the Arthrex Agreement, Angel disposable products were sold at a lower average selling price in 2014 as compared to the prior year. Additionally, machine refurbishment costs increased primarily due to a \$600,000 accrual recorded for the expected refurbishment and design improvements of customer placed machines at December 31, 2014 and as a result of additional refurbishment cost incurred during the year. After all such refurbishments have been completed, we do not expect to incur further costs or expenses in connection therewith.

Operating Expenses

Operating expenses increased \$3,169,000 (15%) to \$24,382,000 comparing the year ended December 31, 2014 to the previous year. A discussion of the various components of Operating expenses follows below.

Salaries and Wages

Salaries and wages increased \$1,154,000 (16%) to \$8,473,000 comparing the year ended December 31, 2014 to the previous year. The increase was primarily due to the planned expansion of our commercial, marketing, and clinical organization which was partially offset by a decrease resulting from the closure of our research and development facility in North Carolina.

Consulting Expenses

Consulting expenses decreased \$748,000 (35%) to \$1,401,000 comparing the year ended December 31, 2014 to the previous year. The decrease was primarily due to lower expenses related to the ALD-401 clinical trial due to the close out of the trial along with lower international sales consulting as we switched our focus to CED and CMS reimbursement matters. Additionally, we had lower business development, Angel product development and quality consulting costs. These were partially offset by higher consulting expense related to the management, promotion, and roll-out of CED protocols and CMS reimbursement matters, employment consultation, and the selection of a business management software.

Professional Fees

Professional fees increased \$65,000 (6%) to \$1,221,000 comparing the year ended December 31, 2014 to the previous year. The increase was primarily due to legal costs related to employment matters and Aurix commercialization partially offset by a decrease in legal costs related to security filings, clinical trial, and business development matters.

Research, Development, Trials and Studies

Research, development, trials and studies expenses decreased \$1,175,000 (31%) to \$2,624,000 comparing the year ended December 31, 2014 to the previous year. The decrease was primarily due to lower ALD-401 clinical trial costs as a result of the close out of the trial, lower costs related to the sourcing and testing of Angel centrifuge replacement components, and lower manufacturing and design fees related to the revision of an Angel disposable product. These were offset by increased CED development costs.

General and Administrative Expenses

General and administrative expenses decreased \$811,000 (12%) to \$5,978,000 comparing the year ended December 31, 2014 to the previous year. The decrease was primarily due to a non-cash charge of \$1,006,000 recognized in 2013 due to the effect of the amendment to the contingent consideration associated with the Aldagen acquisition. We recognized an additional decrease as a result of the closure of our research and development facility, as well as, a decrease to independent sales commissions primarily due to the licensing of Angel to Arthrex in 2013. These were partially offset by higher expenses related to the planned expansion of our commercial organization, product rebranding activities, and the implementation of our protocols under CED, along with higher expenses related to investor services expense. Additionally, the closing of our research and development facility resulted in a loss on abandonment of \$243,000.

Other Income (Expense)

Other expense, net decreased \$6,662,000 (312%) to other income, net of \$4,527,000 comparing the year ended December 31, 2014 to the previous year. The difference was primarily due to the \$8,571,000 change in the fair value of derivative liabilities from an unrealized loss of \$470,000 to an unrealized gain of \$8,101,000 for the years ended December 31, 2013 and 2014, respectively. This was partially offset by higher non-cash interest expense of \$864,000 from the amortization of deferred issuance costs, \$265,000 of non-cash interest expense from the amortization of debt discount, an increase in interest expense of approximately \$399,000 primarily as a result of the Deerfield Facility Agreement and prepayment fees of \$260,000 primarily related to the settlement of a term note. In addition, we recognized a loss on the disposal of fixed assets of approximately \$130,000 in 2014.

Liquidity and Capital Resources

Since inception we have incurred, and continue to incur significant losses from operations. For the year ended December 31, 2014, we have incurred a net loss from operations of approximately \$23.4 million and an accumulated deficit at December 31, 2014 of \$110.1 million. We had working capital at December 31, 2014 of \$13.4 million as compared to a negative working capital of \$0.6 million at December 31, 2013.

Historically, we have financed our operations through a combination of the sale of debt, equity and equity-linked securities, licensing, royalty, and product revenues. If we continue to incur negative cash flow from sources of operating activities for longer than expected, our ability to continue as a going concern could be in substantial doubt and we will require additional funds through debt facilities, and/or public or private equity or debt financings to continue operations. We cannot provide any assurance that we will be able to obtain the capital we require on a timely basis or on terms acceptable to us.

At December 31, 2014, we had approximately \$15.9 million of cash and cash equivalents and long-term convertible debt of \$35 million under the Deerfield Facility Agreement. However, in connection with the Deerfield Facility Agreement (*See Note 11 - Debt for additional details.*), the Company is required to maintain a compensating cash balance of \$5,000,000 in deposit accounts subject to control agreements in favor of the lenders.

In January 2015 we granted to Rohto Pharmaceutical Co., Ltd. a royalty bearing, nontransferable, exclusive license, with limited right to sublicense, to use certain of the Company's intellectual property for the development, import, use, manufacturing, marketing, sale and distribution for all wound care and topical dermatology applications of the Aurix system and related intellectual property and know-how in human and veterinary medicine in Japan in exchange for an upfront payment from Rohto of \$3.0 million (which is reduced by the \$1.5 million payment to Millennia Holdings, as set forth below). In connection with and effective as of the entering into the Rohto Agreement, we executed Amendment No. 5 to the Licensing and Distribution Agreement with Millennia dated September 10, 2009, as subsequently amended to terminate the Millennia Agreement and to allow us to transfer the exclusivity rights from Millennia to Rohto. In connection with this amendment we paid a one-time, non-refundable fee of \$1.5 million to Millennia upon our receipt of the \$3.0 million upfront payment from Rohto to Millennia.

The Company will continue to pursue exploratory conversations with companies regarding their interest in our various products and technologies. We will seek to leverage these relationships if and when they materialize to secure non-dilutive sources of funding. There is no assurance that we will be able to secure such relationships or, even if we do, the terms will be favorable to us.

We estimate that our current resources, expected revenue from current products, including additional revenue expected to be generated from our increased marketing efforts, royalty revenue and license fee revenue will be adequate to maintain our operations through at least 2015. However, if we are unable to increase our revenues as much as expected or if capital infusions are not available to the Company from future strategic partnerships, from the sale of shares under the purchase agreements we entered into with Lincoln Park, or through the sale of debt, equity and equity-linked securities, licensing, or royalty arrangement, then we will be required to curtail portions of our strategic plan. Specific programs that may require additional funding include, without limitation, continued investment in the sales, marketing, distribution, and customer service areas, further expansion into the international markets, significant new product development or modifications, and pursuit of other opportunities. If adequate capital cannot be obtained on a timely basis and on satisfactory terms, the Company's operations could be materially negatively impacted.

Net cash provided by (used in) operating, investing, and financing activities for the years ended December 31, 2014 and 2013 were as follows:

	December 31, 2014	December 31, 2013
	<i>(in millions)</i>	
Cash flows used in operating activities	\$ (17.4)	\$ (11.4)
Cash flows (used in) provided by investing activities	\$ (0.4)	\$ 1.4
Cash flows provided by financing activities	\$ 30.4	\$ 10.7

Operating Activities

Cash used in operating activities in 2014 of \$17.4 million primarily reflects our net loss of \$18.9 million adjusted by a (i) \$8.1 million decrease for changes in derivative liabilities resulting from a change in their fair value, (ii) \$4.7 million increase for the impairment of IPR&D and trademarks due to the discontinuance of our ALD-401 trials, (iii) \$1.7 million increase for amortization of deferred costs and debt discount relating to debt issuances, (iv) \$1.3 million increase for stock-based compensation, (v) \$0.8 million increase for changes in assets and liabilities, (vi) \$0.6 million increase for depreciation and amortization, and (vii) \$0.2 million increase for a loss on the abandonment of the Aldagen North Carolina lease.

Cash used in operating activities in 2013 of \$11.4 million primarily reflects our net loss of \$20.2 million adjusted by a (i) \$5.2 million increase for changes in assets and liabilities, (ii) \$1.1 million increase for depreciation and amortization, (iii) \$1.0 million for the effect of the amendment to the contingent consideration, (iv) \$0.7 million increase for stock-based compensation, (v) \$0.6 million decrease for a gain on disposal of assets, (vi) \$0.5 million increase for change in derivative liabilities, (vii) \$0.3 million increase for the effect of issuance of warrants for term loan modifications, and (viii) \$0.2 million increase for amortization of deferred costs relating to debt issuances.

Investing Activities

Cash (used in) investing activities in 2014 primarily reflects the capitalization of approximately \$0.3 million in business software implementation costs, the purchase of Angel centrifuge devices for internal use and the receipt of \$0.1 million from the sale of assets resulting from the closing of our research and development facility related to the ALD-401 clinical trial. Cash provided by (used in) investing activities in 2013 primarily reflects the purchases of Aurix centrifuge devices and the net activity of purchases and sales of Angel centrifuge devices. In 2013, existing Angel centrifuges with a net book value of \$1.3 million were sold under the Arthrex Agreement. In order to maintain and expand the sales of our products, we will need to continue to purchase Aurix centrifuge devices. Since the inception of the Arthrex Agreement purchases of Angel centrifuge devices are no longer included in investing activities unless purchased for internal use.

Financing Activities

Net cash provided by financing activities was \$30.4 million and \$10.7 million for the years ended December 31, 2014 and 2013, respectively.

	Years Ended December 31,	
	2014	2013
	<i>(in millions)</i>	
Proceeds from the issuance of common stock, net	\$ 3.7	\$ 5.5
Proceeds from the issuance debt, net	32.9	6.2
Debt repayments	(6.2)	(1.0)
Cash flows provided by financing activities	<u>\$ 30.4</u>	<u>\$ 10.7</u>

The following sections provide a more detailed discussion of our cash flows from available financing facilities and activities.

Issuance of Common Stock

Lincoln Park

We raised \$1.8 million and \$0.9 million in the years ended December 31, 2014 and 2013, respectively, from the sale of shares under the purchase agreements entered into with Lincoln Park on February 18, 2013 and October 6, 2010. (See Note 13 — Equity for additional details.)

March 2014 Equity Offering

On March 31, 2014 we raised \$2.0 million, before placement agent's fees and other offering expenses, from the private placement of 3,846,154 shares of common stock (at a price of \$0.52 per share) and five-year stock purchase warrants to purchase 2,884,615 shares of common stock at \$0.52 per shares. We paid \$0.1 million in placement agent fees and other offering expenses related to this raise. (See Note 13 — Equity for additional details)

Common Stock and Warrant Registered Offering

On February 19, 2013, the Company entered into securities purchase agreements with certain institutional accredited investors, including certain current shareholders of the Company, to raise gross proceeds of \$5,000,000, before placement agent's fees and other offering expenses, in a registered offering. The Company issued to the investors units of the Company's securities consisting, in the aggregate, of 9,090,911 shares of the Company's common stock. The purchase price paid by investors was \$0.55 per share. We paid \$0.4 million in placement agent fees and other offering expenses related to this agreement. (See Note 13 — Equity for additional details.)

Debt

Deerfield

On March 31, 2014, we executed agreements with Deerfield for the issuance of a five-year senior secured convertible credit facility. Under the terms of this agreement, Deerfield agreed to provide to us a convertible credit facility in an amount up to \$35 million, before placement agent fees and other offering expenses. We received \$9 million in March 2014 and the remaining disbursement of \$26 million was received in June 2014. (See Note 11 — Debt for additional details) We paid \$2.8 million in placement agent fees and other offering expenses related to this credit facility.

Mid-Cap Financial Term Loan

On February 19, 2013, we entered into a Credit and Security Agreement with Mid-Cap Financial from which we received \$4.5 million, before placement agent fees and other offering expenses, on February 27, 2013. In 2013, we paid principal payments of \$0.8 million. On March 31, 2014, we paid the remaining balance of the term loan of \$3.7 million. We paid \$0.2 million in placement agent fees and other offering expenses related to this loan. (See Note 11 — Debt for additional details)

December 2013 Convertible Bridge Note

On November 21, 2013, we executed agreements with certain investors for the subsequent issuance of 10% subordinated convertible notes and stock purchase warrants, for gross proceeds of \$3 million, before placement agent fees and other offering expenses. We received \$2.25 million of the expected gross proceeds on December 10, 2013. We received \$0.75 million of the gross proceeds in February 2014. In 2013, we paid \$0.3 million in placement agent fees and other offering expenses related to these notes.

On March 31, 2014 the holders of the December 2013 convertible bridge notes (except for one holder), agreed to convert their outstanding notes pursuant to its terms, converting into 5,981,859 shares of common stock. The Company repaid, in its entirety, the portion of the debt excluded from the conversion (including interest and prepayment penalties) pursuant to its terms, for a total cash payment of approximately \$339,000. (See Note 11 — Debt for additional details)

Inflation

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

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements.

Contractual Obligations

Contractual obligations at December 31, 2014	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
Long-Term debt ⁽¹⁾	\$ 44,641,000	\$ 3,101,000	\$ 4,031,000	\$ 37,509,000	\$ -
Operating leases	1,916,000	439,000	914,000	563,000	-
Purchase obligations	2,977,000	2,977,000	-	-	-
	<u>\$ 49,534,000</u>	<u>\$ 6,517,000</u>	<u>\$ 4,945,000</u>	<u>\$ 38,072,000</u>	<u>\$ -</u>

(1) Deerfield \$35 million five-year 5.75% senior secured convertible credit facility due March 31, 2019, including interest. (See Note 11 — Debt for additional details.)

Purchase obligations consist of a commitment to purchase 600 Aurix machines and 273 Angel machines in 2015. Under the obligation to purchase Aurix machines, we purchased 250 machines for \$250,000 in 2013. There were no Aurix machines purchased in 2014. Under the terms of our purchase agreement for Angel machines, we provide an upfront deposit for the purchase of the units and pay the remaining balance upon shipment of the units from our manufacturer. The obligation to purchase Angel machines is based on our deposit balance at December 31, 2014. However, under the agreement we are only obligated to our manufacturer to the extent that machines have been manufactured and parts purchased.

Critical Accounting Policies

In preparing our consolidated financial statements, we make estimates and assumptions that can have a significant impact on our consolidated financial position and results of operations. The application of our critical accounting policies requires an evaluation of a number of complex criteria and significant accounting judgments by us. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Actual results may differ significantly from these estimates under different assumptions, judgments or conditions. We have identified the following policies as critical to our business operations and the understanding of our consolidated results of operations. For further information on our critical and other accounting policies, (See Note 1 – Business and Presentation to our consolidated financial statements).

Stock-Based Compensation

Under the Company's 2002 Long Term Incentive Plan (the "LTIP") and 2013 Equity Incentive Plan (the "EIP"), it grants share-based awards, typically in the form of stock options and stock awards, to eligible employees, directors, and service providers to purchase shares of common stock. The fair values of these awards are determined on the dates of grant or issuance and are recognized as expense over the requisite service periods.

The Company estimates the fair value of stock options on the grant issuance date using the Black-Scholes-Merton option-pricing formula. The determination of fair value using this model requires the use of certain estimates and assumptions that affect the reported amount of compensation cost recognized in the Company's Consolidated Statements of Operations. These include estimates of the expected term of the option, expected volatility of the Company's stock price, expected dividends and the risk-free interest rate. These estimates and assumptions are highly subjective and may result in materially different amounts should circumstances change and the Company employ different assumptions in future periods.

For stock options, expected volatilities are based on historical volatility of the Company's stock. Company data was utilized to estimate option exercises and employee terminations within the valuation model for the year ended December 31, 2014 and the Company used peer company data to estimate option exercises and employee terminations within the valuation model for the year ended December 31, 2013. No cash dividends have ever been declared or paid on the Company's common stock and currently none is anticipated. The risk-free interest rate is based upon U.S. Treasury securities with remaining terms similar to the expected term of the options.

The Company estimates the fair value of stock awards based on the closing market value of the Company's stock on the issuance date of the grant. In certain select cases, the Company has issued stock purchase warrants, outside the LTIP, to service providers in exchange for the performance of consulting or other services. These warrants have generally been immediately vested and expense was recognized equal to the fair value of the warrant on the date of grant using the Black-Scholes option pricing model. The same assumptions (and related risks) as discussed above apply, with the exception of the expected term; for these warrants issued to service providers, the Company estimates that the warrant will be held for the full term.

Business Combinations

The Company accounts for business combinations using the acquisition method. Under this method the Company allocates the purchase price to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition, including intangible assets that arise from contractual or other legal rights or are separable (i.e. capable of being sold, transferred, licensed, rented, or exchanged separately from the entity). Determination of fair value is based on certain estimates and assumptions regarding such things as forecasted future revenues and expenses, customer attrition, prevailing royalty rates, required rates of return, etc. The purchase price in excess of the fair value of the net assets and liabilities is recorded as goodwill.

Revenue Recognition

The Company recognizes revenue in accordance with FASB ASC 605, Revenue Recognition. ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) consideration is fixed or determinable; and (4) collectability is reasonably assured.

Sales of products

The Company provides for the sale of its products, including disposable processing sets and supplies to customers. Revenue from sales products is recognized upon shipment of products to the customers. The Company does not maintain a reserve for returned products as in the past those returns have not been material.

Usage or leasing of blood separation equipment

As a result of the acquisition of the Angel® business in 2010, the Company acquired various multiple element revenue arrangements that combine the (i) usage or leasing of blood separation processing equipment, (ii) maintenance of processing equipment, and (iii) purchase of disposable processing sets and supplies. We assigned these multiple element revenue arrangements to Arthrex on August 7, 2013. (See Note 2 — *Distributor and License Agreement with Arthrex for additional details*) Under these arrangements, the total arrangement consideration was allocated to the various elements based on their relative estimated selling prices. The usage of the blood separation processing equipment was accounted for as an operating lease; since customer payments were contingent upon the customer ordering new products, rental income was recorded following the contingent rental method when rental income was earned and collectability was reasonably assured. The sale of disposable processing sets and supplies and maintenance were deemed a combined unit of accounting; since (a) any consideration for disposable processing sets and supplies and maintenance was contingent upon the customer ordering additional disposable processing sets and supplies and (b) both the disposable products and maintenance services were provided over the same term, we recognized revenue for this combined unit of accounting following the contingent revenue method at the time disposable products were delivered based on prices contained in the agreement.

Percentage-based fees on licensee sales of covered products are generally recorded as products are sold by licensees and are reflected as "Royalties" in the Consolidated Statements of Operations.

Direct costs associated with product sales and royalty revenues are recorded at the time that revenue is recognized.

Goodwill and Intangible Assets

Intangible assets were acquired as part of our acquisition of the Angel business and Aldagen, and consist of definite-lived and indefinite-lived intangible assets, including goodwill.

Definite-lived intangible assets

Our definite-lived intangible assets include trademarks, technology (including patents) and customer relationships, and are amortized over their useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, we test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i. e., the asset is not recoverable), we would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. We periodically reevaluate the useful lives for these intangible assets to determine whether events and circumstances warrant a revision in their remaining useful lives. During the second quarter of 2014 the Company performed an assessment of our trademarks and concluded that the fair value of the trademarks was impaired. (See Note 8 — *Goodwill and Identifiable Intangible Assets for additional information.*)

Indefinite-lived intangible assets

We evaluate our indefinite-lived intangible asset, consisting solely of in-process research and development (“IPR&D”) acquired in the Aldagen acquisition, for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable, and at least on an annual basis on October 1 of each year, by comparing the fair value of the asset with its carrying amount. If the carrying amount of the intangible asset exceeds its fair value, we would recognize an impairment loss in the amount of that excess. During the second quarter of 2014 the Company performed an assessment of our IPR&D and concluded that the fair value of the IPR&D was impaired. (See Note 8 — *Goodwill and Intangible Identifiable Assets for additional information*). Our annual impairment evaluation of indefinite lived intangible assets was performed as of October 1, 2014, and it was determined that there was no additional impairment of the recorded balance.

Goodwill

Goodwill represents the purchase price of acquisitions in excess of the amounts assigned to acquired tangible or intangible assets and assumed liabilities. Amounts allocated to goodwill are tax deductible in all relevant jurisdictions. As a result of our acquisition of Aldagen in February 2012, we recorded goodwill of approximately \$422,000. Prior to the acquisition of Aldagen, we had goodwill of approximately \$707,000 as a result of the acquisition of the Angel business in April 2010.

We conduct an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company’s fair value below its net equity value. During the second quarter of 2014 the Company performed an impairment test of our goodwill and concluded that there was no impairment (See Note 8 — *Goodwill and Identifiable Intangible Assets for additional details*.) Our annual impairment evaluation of goodwill was performed as of October 1, 2014, and it was determined that there was no additional impairment of the recorded balance.

Fair Value Measurements

The balance sheets include various financial instruments that are carried at fair value. Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

- Level 1, defined as observable inputs such as quoted prices in active markets for identical assets;
- Level 2, defined as observable inputs other than Level 1 prices such as quoted prices for similar assets; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

An asset’s or liability’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

The Company accounts for derivative instruments under ASC 815, *Accounting for Derivative Instruments and Hedging Activities*, as amended and interpreted. ASC 815 requires that we recognize all derivatives on the balance sheet at fair value. Certain warrants issued December 2013 and prior met the definition of derivative liabilities. We determine the fair value of these derivative liabilities using the Black-Scholes option pricing model. When determining the fair value of our financial instruments using the Black-Scholes option pricing model, we are required to use various estimates and unobservable inputs, including, among other things, contractual terms of the instruments, expected volatility of our stock price, expected dividends, and the risk-free interest rate. Changes in any of the assumptions related to the unobservable inputs identified above may change the fair value of the instrument. Increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in the unobservable inputs generally result in decreases in fair value.

In March and June 2014, we issued stock purchase warrants and convertible notes that contained embedded conversion options; the embedded conversion options are accounted for as a derivative liability. We determine the fair value of these derivative liabilities using the binomial lattice model. When determining the fair value of our financial instruments using binomial lattice models, we also are required to use various estimates and unobservable inputs, including in addition to those listed above, the probability of certain events.

Changes in fair value are classified in “other income (expense)” in the consolidated statement of operations.

Recent Accounting Pronouncements

ASU No. 2014-09, “Revenue from Contracts with Customers (Topic 606).” The Financial Accounting Standards Board (FASB or Board) and the International Accounting Standards Board (IASB) (collectively, the Boards) jointly issued a long-awaited standard that will supersede virtually all of the revenue recognition guidance in U.S. GAAP. The FASB issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606). The FASB has set an effective date of fiscal years beginning after December 15, 2016. Early adoption is not permitted for public entities. FASB ASU No. 2014-09 will amend FASB Accounting Standards Codification™ (ASC) by creating Topic 606, Revenue from Contracts with Customers and Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. This document reorganizes the guidance contained in FASB ASC 606 (revenue recognition standard), to follow the five step revenue recognition model along with other guidance impacted by this standard. The potential effects of the adoption of ASU 2014-09, Topic 606 on our results of operations and the Company’s consolidated financial statements have not been determined at this time.

ASU No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40)- Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” Under generally accepted accounting principles (GAAP), continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity’s liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Currently, there is no guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern or to provide related footnote disclosures. FASB issued ASU 2014-15 to provide guidance in GAAP about management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact, if any, that the adoption will have on its consolidated financial statements.

ASU No. 2014-16, “Derivatives and Hedging (Topic 815) – Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity.” There are predominantly two methods used in current practice by issuers and investors in evaluating whether the nature of the host contract within a hybrid financial instrument issued in the form of a share is more akin to debt or to equity. Additionally, there is diversity in practice with respect to the consideration of redemption features in relation to other features when determining whether the nature of a host contract is more akin to debt or to equity. The objective of this update is to eliminate the use of different methods in practice and thereby reduce existing diversity under GAAP in the accounting for hybrid financial instruments issued in the form of a share. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption, including adoption in an interim period, is permitted. If an entity early adopts the amendments in an interim period, any adjustments shall be reflected as of the beginning of the fiscal year that includes that interim period. The Company is currently evaluating the impact, if any, that the adoption will have on its consolidated financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable.

ITEM 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of Nuo Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Nuo Therapeutics, Inc. (the "Company") as of December 31, 2014 and 2013, and the consolidated statements of operations, redeemable common stock and stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nuo Therapeutics, Inc. as of December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

/s/ Stegman & Company

Baltimore, Maryland
March 31, 2015

NUO THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 15,946,425	\$ 3,286,713
Short-term investments, restricted	53,391	53,257
Accounts and other receivable, net	1,889,327	3,926,681
Inventory, net	556,620	1,111,507
Prepaid expenses and other current assets	2,338,990	1,258,282
Deferred costs, current portion	1,091,387	316,551
Total current assets	<u>21,876,140</u>	<u>9,952,991</u>
Property and equipment, net	925,171	919,469
Deferred costs	3,547,007	482,349
Intangible assets, net	28,747,770	33,768,954
Goodwill	1,128,517	1,128,517
Total assets	<u>\$ 56,224,605</u>	<u>\$ 46,252,280</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,877,736	\$ 3,351,844
Accrued expenses	6,218,224	4,666,828
Deferred revenues, current portion	402,377	740,990
Note payable, current portion	—	1,800,000
Total current liabilities	<u>8,498,337</u>	<u>10,559,662</u>
Notes payable	—	3,620,593
Convertible debt, net of debt discount	325,553	202,658
Deferred revenues	1,039,475	1,441,852
Derivative liabilities	29,846,821	3,248,595
Other liabilities	546,867	366,926
Total liabilities	<u>40,257,053</u>	<u>19,440,286</u>
Commitments and contingencies (See Note 18)		
Conditionally redeemable common stock (909,091 issued and outstanding)	500,000	500,000
Stockholders' equity		
Common stock; \$.0001 par value, authorized 425,000,000 shares;		
2014 issued and outstanding - 125,680,100 shares;		
2013 issued and outstanding - 107,164,855 shares	12,477	10,626
Common stock issuable	392,950	432,100
Additional paid-in capital	125,173,973	117,097,844
Accumulated deficit	(110,111,848)	(91,228,576)
Total stockholders' equity	<u>15,467,552</u>	<u>26,311,994</u>
Total liabilities and stockholders' equity	<u>\$ 56,224,605</u>	<u>\$ 46,252,280</u>

The accompanying notes are an integral part of these financial statements.

NUO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2014	2013
Revenues		
Product sales	\$ 5,849,330	\$ 10,498,726
License fees	402,264	167,657
Royalties	1,510,340	703,744
Other revenue	—	201,311
Total revenues	<u>7,761,934</u>	<u>11,571,438</u>
Cost of revenues		
Cost of sales	6,594,006	8,363,902
Cost of royalties	176,737	89,290
Total cost of revenues	<u>6,770,743</u>	<u>8,453,192</u>
Gross profit	<u>991,191</u>	<u>3,118,246</u>
Operating expenses		
Salaries and wages	8,473,427	7,319,407
Consulting expenses	1,401,381	2,148,983
Professional fees	1,221,462	1,156,868
Research, development, trials and studies	2,623,541	3,798,398
General and administrative expenses	5,978,429	6,789,660
Impairment of trademarks and IPR&D	4,683,829	—
Total operating expenses	<u>24,382,069</u>	<u>21,213,316</u>
Loss from operations	<u>(23,390,878)</u>	<u>(18,095,070)</u>
Other income (expense)		
Interest, net	(3,434,783)	(1,680,023)
Change in fair value of derivative liabilities	8,100,922	(470,052)
Loss on disposal of fixed assets	(131,456)	—
Other	(7,493)	15,374
Total other income (expenses)	<u>4,527,190</u>	<u>(2,134,701)</u>
Loss before provision for income taxes	<u>(18,863,688)</u>	<u>(20,229,771)</u>
Income tax provision	19,584	18,589
Net loss	<u>(18,883,272)</u>	<u>(20,248,360)</u>
Loss per common share — Basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.20)</u>
Weighted average shares outstanding — Basic and diluted	<u>120,516,225</u>	<u>103,620,046</u>

The accompanying notes are an integral part of these financial statements.

NUO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY

	Redeemable Common Stock	Common Stock		Additional Paid-in Capital	Common Stock Issuable	Accumulated Deficit	Total Stockholders' Equity
		Shares	Amount				
Balance at January 1, 2013	\$ —	93,808,386	\$ 9,381	\$ 108,485,646	\$ 489,100	\$ (70,980,216)	\$ 38,003,911
Amendment to contingent consideration for Aldagen acquisition	—	—	—	1,006,159	—	—	1,006,159
Warrants issued for credit and security agreement	—	—	—	580,394	—	—	580,394
Warrants issued for term loan modification	—	—	—	455,275	—	—	455,275
Common stock issued for release of security interest in patents	—	250,000	25	325,668	—	—	325,693
Common stock issued upon conversion of 4% Convertible Promissory Note	—	1,600,219	160	523,767	—	—	523,927
Common stock issued pursuant to private offering completed in First Quarter	500,000	9,090,911	818	4,056,370	—	—	4,057,188
Common stock issued pursuant to equity purchase agreements executed in October 2010	—	450,000	45	302,955	—	—	303,000
Common stock issued pursuant to equity purchase agreements executed in February 2013	—	1,890,261	189	601,756	—	—	601,945
Common stock issued to holder of pre-bankruptcy Series A Preferred stock, pursuant to reorganization plan	—	27,000	3	39,147	(39,150)	—	—
Stock-based compensation related to stock, options and warrants issued for services rendered by—							
Employees and Directors	—	—	—	676,185	—	—	676,185
Other parties	—	37,500	4	44,524	(17,850)	—	26,678
Other changes	—	10,578	1	(2)	—	—	(1)
Net loss	—	—	—	—	—	(20,248,360)	(20,248,360)
Balance at December 31, 2013	\$ 500,000	107,164,855	\$ 10,626	\$ 117,097,844	\$ 432,100	\$ (91,228,576)	\$ 26,311,994

NUO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY

	Redeemable Common Stock	Common Stock		Additional Paid-in Capital	Common Stock Issuable	Accumulated Deficit	Total Stockholders Equity
		Shares	Amount				
Common stock issued pursuant to equity purchase agreements executed in February 2013	—	3,793,865	379	1,754,186	—	—	1,754,565
Common stock issued upon conversion of 4% Convertible Promissory Note	—	886,690	89	456,673	—	—	456,762
Common stock issued upon conversion of 10% Convertible Promissory Note	—	5,981,859	598	1,375,374	—	—	1,375,972
Common stock issued pursuant to private offering completed in March 2014	—	3,846,154	384	1,911,311	—	—	1,911,695
Warrants issued in connection with private offering completed in March 2014	—	—	—	(1,121,235)	—	—	(1,121,235)
Expiration of December 2013 Bridge Note warrant provisions in June 2014	—	—	—	1,331,776	—	—	1,331,776
Common stock issued to holder of pre-bankruptcy Series A Preferred stock, pursuant to reorganization plan	—	27,000	3	39,147	(39,150)	—	—
Common stock issued in connection with the Deerfield Facility	—	2,709,677	271	1,049,729	—	—	1,050,000
Common stock issued pursuant to the second amendment to the Aldagen Holding LLC exchange and purchase agreement	—	1,270,000	127	(127)	—	—	—
Stock-based compensation related to stock, options and warrants issued for services rendered	—	—	—	1,279,295	—	—	1,279,295
Net loss	—	—	—	—	—	(18,883,272)	(18,883,272)
Balance at December 31, 2014	\$ 500,000	125,680,100	\$ 12,477	\$ 125,173,973	\$ 392,950	\$(110,111,848)	\$ 15,467,552

The accompanying notes are an integral part of these financial statements.

NUO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (18,883,272)	\$ (20,248,360)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt expense	31,773	75,165
Loss on reserve for inventory obsolescence	90,000	—
Depreciation and amortization	613,500	1,092,143
Stock-based compensation	1,279,295	717,863
Change in fair value of derivative liabilities	(8,100,922)	470,052
Non-cash interest expense:		
Amortization of deferred costs	1,112,890	248,606
Amortization of debt discount	589,692	323,146
Deferred income tax provision	19,584	18,589
Loss (Gain) on disposal of assets	131,456	(594,173)
Loss on abandonment of lease	242,466	—
Impairment of IPR&D and trademarks	4,683,829	—
Effect of amendment to contingent consideration	—	1,006,159
Loss on extinguishment of debt	—	19,868
Effect of issuance of warrants for term loan modification	—	303,517
Change in operating assets and liabilities, net of those acquired:		
Accounts and other receivable, net	2,005,581	(2,268,104)
Inventory	464,887	58,590
Prepaid expenses and other current assets	(1,080,842)	(210,153)
Accounts payable	(1,474,108)	1,917,680
Accrued expenses	1,570,877	3,288,621
Deferred revenues	(740,990)	2,182,842
Other liabilities	21,034	196,953
Net cash used in operating activities	(17,423,270)	(11,400,996)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment acquisitions	(482,962)	(750,697)
Proceeds from sale of equipment	133,767	2,139,672
Net cash provided by (used in) investing activities	(349,195)	1,388,975
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of debt, net	32,967,060	6,240,797
Proceeds from issuance of common stock, net	3,666,260	5,462,132
Repayment of note payable	(6,201,143)	(1,020,000)
Net cash provided by financing activities	30,432,177	10,682,929
Net increase in cash	12,659,712	670,908
Cash, beginning of period	3,286,713	2,615,805
Cash, end of period	\$ 15,946,425	\$ 3,286,713

The accompanying notes are an integral part of these financial statements.

NUO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Business and Presentation

Description of Business

At our 2014 Annual Meeting, our shareholders voted to approve the name change amendment to our Certificate of Incorporation. The new name of our Company is “Nuo Therapeutics, Inc.” and the name change was effective upon filing of the Certificate of Amendment to our Certificate of Incorporation in the State of Delaware. Nuo Therapeutics, Inc., formerly Cytomedix, Inc., (“Nuo Therapeutics,” the “Company,” “we,” “us,” or “our”) is a biomedical company marketing products within the U.S. and internationally. We commercialize innovative cell-based technologies that harness the regenerative capacity of the human body to trigger natural healing. The use of autologous from self-biological therapies for tissue repair and regeneration is part of a transformative clinical strategy designed to improve long term recovery in complex chronic conditions with significant unmet medical needs. Growth drivers in the U.S. include Medicare coverage for the treatment of chronic wounds under a National Coverage Determination when registry data is collected under Coverage with Evidence Development (“CED”), and a worldwide distribution and licensing agreement that allows our partner to promote the Angel System for all uses other than wound care.

Our current commercial offerings consist of point of care technologies for the safe and efficient separation of autologous blood and bone marrow to produce platelet based therapies or cell concentrates. We currently have two distinct platelet rich plasma (“PRP”) devices, the Aurix™ System (*formerly known as the AutoloGel™ System*) for wound care and the Angel™ concentrated Platelet Rich Plasma (“cPRP”) System for orthopedics markets. Approximately 73% of our sales are in the United States, where we sell our products through direct sales representatives and distributors. Since August 8, 2013, Arthrex, Inc. (“Arthrex”), as our exclusive distributor for Angel, accounted for 100% of our Angel sales.

Since our inception, we have financed our operations by raising debt, issuing equity and equity-linked instruments, licensing arrangements, royalties, and product revenues. We have incurred, and continue to incur, recurring losses and negative cash flows. On March 31, 2014, we entered into a \$35,000,000 convertible debt facility, \$9,000,000 of which was funded on March 31, 2014 and the remaining \$26,000,000 was funded on June 25, 2014. In addition, on March 31, 2014 we raised \$2.0 million of gross proceeds from the sale of our common stock and warrants to an accredited investor (*See Note 11 – Debt and Note 13- Equity for additional details.*) We used approximately \$5.9 million of the net proceeds from these transactions to retire outstanding debt and interest, approximately \$0.3 million to repay a portion of previously outstanding convertible debt and interest, and we converted approximately \$3.1 million previously outstanding convertible debt and interest into common stock (*See Note 11 - Debt for additional details.*)

At December 31, 2014, we had approximately \$15.9 million of cash on hand. Our operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet our obligations as they become due. We believe that our current resources, expected revenue from current products, including additional revenue expected to be generated from our increased marketing efforts, royalty revenue and license fee revenue will be adequate to maintain our operations through at least the end of 2015. Accordingly, management believes the going-concern basis is appropriate for the accompanying consolidated financial statements.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. Certain prior period information has been reclassified to conform to the current period presentation.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned and controlled subsidiary. All significant inter-company accounts and transactions are eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, valuation of derivative liabilities, valuation and probability of contingent liabilities, fair value of long-lived assets, deferred taxes and associated valuation allowance, and the depreciable lives of fixed assets (including intangible assets and goodwill). Actual results could differ from those estimates.

Cash Equivalents

We consider all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents.

In connection with the Deerfield Facility Agreement (*See Note 7 - Debt for additional details*), the Company is required to maintain a compensating cash balance of \$5,000,000 in deposit accounts subject to control agreements in favor of the lenders.

Approximately \$15,486,000 and \$2,667,000 held in financial institutions was in excess of FDIC insurance at December 31, 2014 and 2013 respectively.

Accounts Receivable and Credit Concentration

We generate accounts receivable from the sale of our products. Our trade receivables balance at December 31, 2014 was primarily from Arthrex (64%). In addition, Arthrex accounted for 91% and 47% of total products sales in 2014 and 2013, respectively. No other single customer accounted for more than 5% of total product sales.

We provide for a reserve against receivables for estimated losses that may result from a customer's inability or unwillingness to pay. The allowance for doubtful accounts is estimated primarily based upon historical write-off percentages, known problem accounts, and current economic conditions. Accounts are written off against the allowance for doubtful accounts when we determine that amounts are not collectable. Recoveries of previously written-off accounts are recorded when collected. At December 31, 2014 and December 31, 2013, we maintained an allowance for doubtful accounts of \$32,000 and \$16,000, respectively.

We use single suppliers for several components of the Angel and Aurix[™] product lines. We outsource the manufacturing of various products, including component parts for Angel, to contract manufacturers. While we believe these manufacturers to demonstrate competency, reliability and stability, there is no assurance that one or more of them will not experience an interruption or inability to provide us with the products needed to satisfy customer demand. Additionally, while most of the components of Aurix[™] are generally readily available on the open market, a reagent, bovine thrombin, is available exclusively through Pfizer, with whom we have an established vendor relationship.

During 2014 and 2015, we devoted substantial resources to enhancing and improving the Angel Product Line to meet new and additional regulatory requirements. During the period that we have been implementing the modifications, we were unable to meet our customer's demand for Angel devices. As a result, our sales were lower than expected and in addition, we incurred a charge to earnings of \$600,000 during the year ended December 31, 2014, reflecting our expected costs for refurbishment and design improvements for the units in circulation. Although we believe that we have completed all the necessary design modifications to the Angel Products, we cannot be sure that we will not continue to experience delays and additional costs in the future.

Inventory

The Company's inventory is produced by third party manufacturers and consists primarily of finished goods. Inventory cost is determined on a first-in, first-out basis and is stated at the lower of cost or net realizable value. The Company maintains an inventory of kits, reagents, and other disposables that have shelf lives that generally range from 18 months to five years. We provide for a reserve against inventory for estimated losses that may result in excess and obsolete inventory (i.e. from the expiration of products).

The Company's reserve for expired inventory is estimated based upon the inventory's remaining shelf life and our anticipated ability to sell such inventory, which is estimated utilizing historical usage and future forecasts, within its remaining shelf life. At December 31, 2014 and 2013 the Company maintained a reserve for expired and excess and obsolete inventory of \$90,000 and \$0, respectively. Expired products are segregated and used for demonstration purposes only; the Company records the associated expense for this reserve to cost of sales on the consolidated statement of operations.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and is depreciated, using the straight-line method, over its estimated useful life ranging from three to five years for all assets except for furniture, lab, and manufacturing equipment which is depreciated over seven and ten years, respectively. Leasehold improvements are stated at cost less accumulated depreciation and is depreciated, using the straight-line method, over the lesser of the expected lease term or its estimated useful life ranging from three to six years. Amortization of leasehold improvements is included in depreciation expense. Maintenance and repairs are charged to operations as incurred. When assets are disposed of, the cost and related accumulated depreciation are removed from the accounts and any gain or loss is included in other income (expense).

Centrifuges may be sold, leased, or placed at no charge with customers. Depreciation expense for centrifuges that are available for sale, leased, or placed at no charge with customers are charged to cost of sales. Angel centrifuges are sold directly to our worldwide distributor, Arthrex, and unless used for internal purposes, no longer recorded as property and equipment. When Angel centrifuges were sold to Arthrex for the year ended 2013, the net book value was charged to cost of sales. Depreciation expense for centrifuges used for sales and marketing and other internal purposes are charged to operations.

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets.

Exit Activities

On May 5, 2014, we announced preliminary efficacy and safety results of our RECOVER-Stroke Phase 2 clinical trial in patients with neurological damage arising from ischemic stroke and treated with ALD-401. Observed improvements in the primary endpoint (mean modified Rankin Score or mRS) of the trial were not clinically or statistically significant. In light of this outcome, we discontinued further funding of the ALD-401 development program, decided to close our facilities in Durham, NC, and terminated certain employees.

The discontinuance of this development program is considered an exit activity. As such, we recognized the following expenses in the second and third quarters of 2014:

	Quarter ended	
	June 30, 2014	September 30, 2014
Severance costs	\$ 320,000	\$ -
Loss on abandonment of lease	-	243,000
Loss on disposal of assets	-	132,000
Total	\$ 320,000	\$ 375,000

An accrual of approximately \$413,000 for the loss on abandonment of the lease, remained at December 31, 2014. The accrued loss will be amortized over the life of the lease against future rental payments made and sublet income payments received. Severance expense is classified as “salaries and wages” and the loss on abandonment and loss on disposal of assets is classified in “Other income (expense) Loss on disposal of fixed assets” in the accompanying consolidated statements of operations. The accrued loss on abandonment is included in accrued expenses and other liabilities in the accompanying consolidated balance sheets.

Intangible Assets and Goodwill

Intangible assets were acquired as part of our acquisition of the Angel business and Aldagen, and consist of definite-lived and indefinite-lived intangible assets, including goodwill.

Definite-lived intangible assets

Our definite-lived intangible assets include trademarks, technology (including patents) and customer relationships, and are amortized over their useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, we test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), we would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. We periodically reevaluate the useful lives for these intangible assets to determine whether events and circumstances warrant a revision in their remaining useful lives. During the second quarter of 2014, as a result of recent events and changes in circumstances, the Company performed an assessment of our trademarks and concluded that the carrying value of the trademarks was impaired. (See Note 8 — Goodwill and Identifiable Intangible Assets for additional details.)

Indefinite-lived intangible assets

We evaluate our indefinite-lived intangible asset, consisting solely of in-process research and development (“IPR&D”) acquired in the Aldagen acquisition, for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable, and at least on an annual basis on October 1 of each year, by comparing the fair value of the asset with its carrying amount. If the carrying amount of the intangible asset exceeds its fair value, we would recognize an impairment loss in the amount of that excess. During the second quarter of 2014 the Company performed an assessment of our IPR&D as of June 30, 2014, as a result of recent events and changes in circumstances, and concluded that the carrying value of the IPR&D was impaired. Our annual impairment evaluation of indefinite lived intangible assets was performed as of October 1, 2014, and it was determined that there was no additional impairment of the recorded balances. (See Note 8 — Goodwill and Identifiable Intangible Assets for additional details.)

Goodwill

Goodwill represents the purchase price of acquisitions in excess of the amounts assigned to acquired tangible or intangible assets and assumed liabilities. Amounts allocated to goodwill are tax deductible in all relevant jurisdictions. As a result of our acquisition of Aldagen in February 2012, we recorded goodwill of approximately \$422,000. Prior to the acquisition of Aldagen, we had goodwill of approximately \$707,000 as a result of the acquisition of the Angel business in April 2010.

We conduct an impairment test of goodwill on an annual basis as of October 1 of each year, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value impaired. The Company conducted an impairment test of our Goodwill as of June 30, 2014, as a result of recent events and changes in circumstances, and concluded that Goodwill was not impaired. (*See Note 5 — Goodwill and Intangible Assets for additional details*) The Company also conducted an impairment test of our Goodwill as of October 1, 2014, and concluded that Goodwill was not impaired.

Conditionally Redeemable Common Stock

The Maryland Venture Fund ("MVF," part of Maryland Department of Business and Economic Development) has an investment in our common stock, and can require us to repurchase the common stock, at MVF's option, upon certain events outside of our control; provided, however, that in the event that, at the time of either such event our securities are listed on a national securities exchange, the foregoing repurchase will not be triggered. MVF's common stock are classified as "contingently redeemable common shares" in the accompanying consolidated balance sheets.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted.

For the year ended December 31, 2014, the income tax provision relates exclusively to a deferred tax liability associated with the amortization of goodwill. The Company has analyzed filing positions in all of the federal and state jurisdictions where it is required to file income tax returns, as well as all open tax years in these jurisdictions. All tax years are subject to examination for the Company's federal return due to our net operating loss carry-forward. The Company believes that its income tax filing positions and deductions would be sustained on audit and does not anticipate any adjustments that would result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded.

The Company's policy for recording interest and penalties associated with audits is to record such items as a component of income before taxes. There were no such items for 2014 and 2013.

Revenue Recognition

We recognize revenue when the four basic criteria for recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) consideration is fixed or determinable; and (4) collectability is reasonably assured.

Sales of products

We provide for the sale of our products, including disposable processing sets and supplies to customers. Revenue from the sale of products is recognized upon shipment of products to the customers. We do not maintain a reserve for returned products as in the past those returns have not been material and are not expected to be material in the future.

Usage or leasing of blood separation equipment

As a result of the acquisition of the Angel[™] business in 2010, we acquired various multiple element revenue arrangements that combine the (i) usage or leasing of blood separation processing equipment, (ii) maintenance of processing equipment, and (iii) purchase of disposable processing sets and supplies. We assigned these multiple element revenue arrangements to Arthrex on August 7, 2013. (See Note 3 — *Distribution and License Agreement with Arthrex for additional details*) Under these arrangements, the total arrangement consideration was allocated to the various elements based on their relative estimated selling prices. The usage of the blood separation processing equipment was accounted for as an operating lease; since customer payments were contingent upon the customer ordering new products, rental income was recorded following the contingent rental method when rental income was earned and collectability was reasonably assured. The sale of disposable processing sets and supplies and maintenance were deemed a combined unit of accounting; since (a) any consideration for disposable processing sets and supplies and maintenance was contingent upon the customer ordering additional disposable processing sets and supplies and (b) both the disposable products and maintenance services were provided over the same term, we recognized revenue for this combined unit of accounting following the contingent revenue method at the time disposable products were delivered based on prices contained in the agreement.

Percentage-based fees on licensee sales of covered products are generally recorded as products are sold by licensees and are reflected as “Royalties” in the consolidated statements of operations. Direct costs associated with product sales and royalty revenues are recorded at the time that revenue is recognized.

Deferred revenue at December 31, 2014 consists of prepaid licensing revenue of approximately \$1,442,000. Revenue of approximately \$402,000 related to the prepaid license was recognized during the year ended December 31, 2014. On January 1, 2013 a medical device excise tax came into effect that required manufacturers to pay tax of 2.3% on the sale of certain medical devices. We report the medical device excise tax on a gross basis, recognizing the tax as both revenue and cost of sales.

Segments and Geographic Information

We operate in one business segment. Approximately 27% and 9% of our product sales were generated outside of the United States for the years ended December 31, 2014 and 2013, respectively.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily consist of expenses relating to product development. Research and development costs do not include salaries and wages, which are included in “Salaries and Wages” in the Consolidated Statements of Operations, and the allocation of overhead and other indirect costs, which are included in the “Consulting expenses” and “General and Administrative expenses” lines in the Consolidated Statements of Operations.

Stock-Based Compensation

The Company, from time to time, may issue stock options or stock awards to employees, directors, consultants, and other service providers under its 2002 Long-Term Incentive Plan (“LTIP”) or 2013 Equity Incentive Plan (“EIP”). In some cases, it has issued compensatory warrants to service providers outside the LTIP or EIP (See Note 13 – *Equity for additional detail*).

All equity-based compensation is estimated on the issuance date of grant using the Black-Scholes-Merton option-pricing formula. The assumptions used in the model for the LTIP and EIP are summarized in the following table:

	2014	2013
Risk free rate	0.1-1.7%	0.4-1.4%
Weighted average expected years until exercise	6.3	5.9
Expected stock volatility	118-127%	96-135%
Dividend yield	—	—

For stock options, expected volatilities are based on historical volatility of the Company's stock. Company data was utilized to estimate option exercises and employee terminations within the valuation model for the year ended December 31, 2014 and peer company data to estimate option exercises and employee terminations within the valuation model for the year ended December 31, 2013. Expected years until exercise represents the period of time that options are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company estimated that the dividend rate on its Common stock will be zero.

The fair value of stock options or compensatory warrants issued to service providers utilizes the same methodology with the exception of the expected term. For these awards to non-employees, the Company estimates that the options or warrants will be held for the full term.

Stock-based compensation for awards granted to non-employees is periodically remeasured as the underlying options and warrants vest. The Company recognizes an expense for such awards throughout the performance period as the services are provided by the non-employees, based on the fair value of these options and warrants at each reporting period.

The Company estimates the fair value of stock awards based on the closing market value of the Company's stock on the date of grant.

Basic and Diluted Earnings (Loss) per Share

Basic earnings (loss) per share is computed by dividing net income (loss) available to common shareholders by the weighted average number of shares of common stock outstanding during the period.

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

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The total number of anti-dilutive shares, common stock options, warrants exercisable for common stock, convertible preferred stock and convertible debt, which have been excluded from the computation of diluted earnings (loss) per share, were 200,989,054 and 61,134,957 for the years ended December 31, 2014 and 2013, respectively.

Defined Contribution Plans

The Company sponsors a defined contribution plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time U.S. employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. Participants are always fully vested in their contributions. The Company makes employer matching contributions, which also vest immediately. This plan is designated as a "Safe Harbor" plan. During 2014 and 2013, the Company contributed approximately \$175,000 and \$164,000 in cash to the plan.

Recent Accounting Pronouncements

ASU No. 2014-09, "Revenue from Contracts with Customers (Topic 606)." The Financial Accounting Standards Board (FASB or Board) and the International Accounting Standards Board (IASB) (collectively, the Boards) jointly issued a long-awaited standard that will supersede virtually all of the revenue recognition guidance in U.S. GAAP. The FASB issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606). The FASB has set an effective date of fiscal years beginning after December 15, 2016. Early adoption is not permitted for public entities. FASB ASU No. 2014-09 will amend FASB Accounting Standards Codification™ (ASC) by creating Topic 606, Revenue from Contracts with Customers and Subtopic 340-40, Other Assets and Deferred Costs—Contracts with Customers. This document reorganizes the guidance contained in FASB ASC 606 (revenue recognition standard), to follow the five step revenue recognition model along with other guidance impacted by this standard. The potential effects of the adoption of ASU 2014-09, Topic 606 on our results of operations and the Company's consolidated financial statements have not been determined at this time.

ASU No. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40) - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." Under generally accepted accounting principles (GAAP), continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Previously, there was no guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. FASB issued ASU 2014-15 to provide guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. The amendments in this Update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact, if any, that the adoption will have on its consolidated financial statements.

ASU No. 2014-16, "Derivatives and Hedging (Topic 815) – Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity." There are predominantly two methods used in current practice by issuers and investors in evaluating whether the nature of the host contract within a hybrid financial instrument issued in the form of a share is more akin to debt or to equity. Additionally, there is diversity in practice with respect to the consideration of redemption features in relation to other features when determining whether the nature of a host contract is more akin to debt or to equity. The objective of this update is to eliminate the use of different methods in practice and thereby reduce existing diversity under GAAP in the accounting for hybrid financial instruments issued in the form of a share. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption, including adoption in an interim period, is permitted. If an entity early adopts the amendments in an interim period, any adjustments shall be reflected as of the beginning of the fiscal year that includes that interim period. The Company is currently evaluating the impact, if any, that the adoption will have on its consolidated financial statements.

Note 2 — Arthrex Distributor and License Agreement

Arthrex Distributor and License Agreement

On August 7, 2013, the Company entered into a Distributor and License Agreement (the "Arthrex Agreement") with Arthrex, Inc., a privately held Florida based company ("Arthrex"). Under the terms of the Arthrex Agreement, Arthrex obtained the exclusive rights to sell, distribute, and service the Company's Angel Concentrated Platelet System and ActivAt ("Products"), throughout the world, for all uses other than chronic wound care. The Company granted Arthrex a limited license to use the Company's intellectual property as part of enabling Arthrex to sell the Products. Arthrex will purchase Products from the Company to distribute and service at certain purchase prices, which may be changed after an initial period. Arthrex has the right, on written notice to the Company, to assume responsibility for the manufacture and supply of the Products, either by assuming the Company's existing manufacturing and supply agreements or by entering into new manufacturing and supply agreements. Arthrex will also pay a certain royalty rate based upon volume of the Products sold. The exclusive nature of Arthrex rights to sell, distribute and service the Products is subject certain existing supply and distribution agreements such that Arthrex may instruct the Company to terminate or not renew any of such agreements. In addition, Arthrex's rights to sell, distribute and service the Products is not exclusive in the non-surgical dermal and non-surgical aesthetics markets. In connection with execution of the Arthrex Agreement, Arthrex paid the Company a nonrefundable upfront payment of \$5 million. The term of the Arthrex Agreement is five years, automatically renewable for an additional three-year period unless Arthrex gives the Company a termination notice at least one year in advance of the end of the initial five-year period. The Arthrex Agreement contains other terms and provisions that are customary to the agreements of this nature. The foregoing description of the Arthrex Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Arthrex Agreement.

Immediately following the execution of the Arthrex Agreement, the Company, at the request of Arthrex, agreed to temporarily provide certain services to Arthrex during a transition period (“Transition Services”). These Transition Services primarily involved customer service, sales order fulfillment, customer billing and collections, and technical support for the Products. For these services, Arthrex paid the Company an agreed upon fee. The Transition Services period was concluded in the fourth quarter of 2013.

Note 3 — Fair Value Measurements

Our balance sheets include various financial instruments that are carried at fair value. Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

- Level 1, defined as observable inputs such as quoted prices in active markets for identical assets;
- Level 2, defined as observable inputs other than Level 1 prices such as quoted prices for similar assets; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

An asset’s or liability’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

Financial Instruments Carried at Cost

Short-term financial instruments in our consolidated balance, including accounts receivable, accounts payable and accrued expenses, are carried at cost which approximates fair value, due to their short-term nature. The face value of our long-term convertible debt approximates its fair value.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We have segregated our financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. The inputs used in measuring the fair value of cash and short-term investments are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds.

We account for our derivative financial instruments, consisting solely of certain stock purchase warrants that contain non-standard anti-dilutions provisions and/or cash settlement features, and certain conversion options embedded in our convertible instruments, at fair value using level 3 inputs. We determine the fair value of these derivative liabilities using the Black-Scholes option pricing model when appropriate, and in certain circumstances using binomial lattice models or other accepted valuation practices.

When determining the fair value of our financial assets and liabilities using the Black-Scholes option pricing model, we are required to use various estimates and unobservable inputs, including, among other things, contractual terms of the instruments, expected volatility of our stock price, expected dividends, and the risk-free interest rate. Changes in any of the assumptions related to the unobservable inputs identified above may change the fair value of the instrument. Increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in the unobservable inputs generally result in decreases in fair value.

When determining the fair value of our financial assets and liabilities using binomial lattice models or other accepted valuation practices, we also are required to use various estimates and unobservable inputs, including in addition to those listed above, the probability of certain events.

The following table represents the fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis for the year ended December 31, 2014 and 2013:

Description	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Assets				
Investment in money market funds	\$ 15,736,350	\$ -	\$ -	\$ 15,736,350
Total investment in money market funds	<u>\$ 15,736,350</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 15,736,350</u>
Liabilities				
Embedded conversion options	\$ -	\$ -	\$ 4,362,225	\$ 4,362,225
Stock purchase warrants	-	-	25,484,596	25,484,596
Total derivative liabilities	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 29,846,821</u>	<u>\$ 29,846,821</u>
Description	As of December 31, 2013			
	Level 1	Level 2	Level 3	Total
Assets				
Investment in money market funds	\$ 2,303,556	\$ -	\$ -	\$ 2,303,556
Total investment in money market funds	<u>\$ 2,303,556</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 2,303,556</u>
Liabilities				
Embedded conversion options	\$ -	\$ -	\$ 1,515,540	\$ 1,515,540
Stock purchase warrants	-	-	1,733,055	1,733,055
Total derivative liabilities	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,248,595</u>	<u>\$ 3,248,595</u>

The Level 1 assets measured at fair value in the above table are classified as “cash and cash equivalents” in the accompanying consolidated balance sheets.

The Level 3 liabilities measured at fair value in the above table are classified as “derivative liabilities” in the accompanying consolidated balance sheets. All other gains and losses in the fair value of derivative instruments are classified as the “change in the fair value of derivative instruments” in the accompanying consolidated statements of operations.

During the years ended December 31, 2014 and 2013, we did not have any transfers between Level 1, Level 2, or Level 3 assets or liabilities.

The following tables set forth a summary of changes in the fair value of Level 3 liabilities measured at fair value on a recurring basis for the year ended December 31, 2014 and 2013:

Description	Balance at January 1, 2014	Established in 2014	Modification of Convertible Debt Agreement	Effect of Conversion to Common Stock	Change in Fair Value	Reclass to Equity (1)	Balance at December 31, 2014
Derivative liabilities:							
Embedded conversion options	\$ 1,515,540	\$ 8,825,935	\$ -	\$ (1,932,693)	\$ (4,046,557)	\$ -	\$ 4,362,225
Stock purchase warrants	1,733,055	29,137,682	-	-	(4,054,365)	(1,331,776)	25,484,596

Description	Balance at January 1, 2013	Established in 2013	Modification of Convertible Debt Agreement	Conversion to Common Stock	Change in Fair Value	Reclass to Equity	Balance at December 31, 2013
Derivative liabilities:							
Embedded conversion options	\$ 780,960	\$ 965,484	\$ 250,361	\$ (393,948)	\$ 90,839	\$ (178,156)	\$ 1,515,540
Stock purchase warrants	-	1,353,842	-	-	379,213	-	1,733,055

(1) Various warrants were reclassified to additional paid-in capital as a result of the expiration of non-standard anti-dilution clauses contained within the warrants.

In February 2014, we purchased a Certificate of Deposit ("CD") from a commercial bank in the amount of \$53,000. The CD bears interest at an annual rate of 0.10% and matures on June 24, 2015. The \$53,000 carrying value of the CD approximates its fair value. This CD collateralizes a letter of credit. (See Note 17 – Commitments and Contingencies for additional details)

We have no financial assets and liabilities measured at fair value on a nonrecurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

Property and equipment, intangible assets and goodwill are measured at fair value on a non-recurring basis (upon impairment). The intangible assets in the table below are measured at fair value on a non-recurring basis and are presented at fair value as of the date of impairment.

(See Note 8 — Goodwill and Identifiable Intangible Assets for additional details)

We determined the fair value for IPR&D by using the royalty savings method of the income approach. In applying this method, we used the existing royalty income that was being generated by the Company and expected future royalty revenues to get to the expected net cash flows. We then applied an asset-specific discount rate to the forecasted net cash flows to arrive at a net present value amount. Significant estimates and assumptions used in this approach were the (i) amount and timing of the projected revenues; (ii) royalty rate based on comparable IPR&D; (iii) discount rate, which reflects the various risks involved in future cash flows; and (iv) tax rate.

We determined the fair value for the Trademark by using the royalty savings method of the income approach. In applying this method, we used the expected future royalty revenues, generated by the Trademark, to get to the expected net cash flows. We then applied an asset-specific discount rate to the forecasted net cash flows to arrive at a net present value amount. Significant estimates and assumptions used in this approach were the (i) amount and timing of the projected revenues; (ii) royalty rate based on comparable trademarks; (iii) estimated useful life; and (iv) discount rate, which reflects the various risks involved in future cash flows; and (v) tax rate.

The following table represents the fair value hierarchy for our non-financial assets that were measured during 2014 (we did not remeasure any of our non-financial assets during 2013):

	Level 1	Level 2	Level 3	Total
Intangible assets				
Intangible assets - IPR&D	\$ —	\$ —	\$ 25,926,000	\$ 25,926,000
Intangible assets - Trademarks	—	—	706,229	706,229
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 26,632,229</u>	<u>\$ 26,632,229</u>

The carrying fair value of our Aldagen related trademarks and in-process research and development reflect a reduction in their value of approximately \$1,025,000 and \$3,659,000, respectively, as a result of an impairment loss recognized during the year ended December 31, 2014. These assets are included in “intangible assets, net” in the accompanying consolidated balance sheets. The reduction in value, as of the valuation date is reflected as “Impairment of IPR&D and trademarks” in the accompanying consolidated statements of operations. These assets are not measured at fair value on a recurring basis.

We have no non-financial assets and liabilities measured at fair value on a recurring basis.

Note 4 — Receivables

Accounts and royalties receivable, net consisted of the following:

	December 31, 2014	December 31, 2013
Trade receivables	\$ 609,179	\$ 2,449,199
Other receivables	1,312,617	1,493,979
	<u>1,921,796</u>	<u>3,943,178</u>
Less allowance for doubtful accounts	<u>(32,469)</u>	<u>(16,497)</u>
	<u>\$ 1,889,327</u>	<u>\$ 3,926,681</u>

Other receivables consist primarily of royalties and transition service fees due from Arthrex and the cost of raw materials needed to manufacture the Angel products that are sourced by the Company and immediately resold, at cost, to the contract manufacturer.

The following table reflects the approximate change in allowance for doubtful accounts.

	Balance at Beginning of Period	Charged to Costs and Expenses	Balances charged-off	Balance at End of Period
Year Ended December 31, 2014				
Allowance for doubtful accounts	\$ 16,497	\$ 31,773	\$ (15,801)	\$ 32,469
Year Ended December 31, 2013				
Allowance for doubtful accounts	\$ 42,709	\$ 75,166	\$ (101,378)	\$ 16,497

Note 5 — Inventory

Inventory, net consisted of the following:

	December 31, 2014	December 31, 2013
Raw materials	\$ 121,631	\$ 125,583
Finished goods	524,989	985,924
	<u>646,620</u>	<u>1,111,507</u>
Less provision for inventory obsolescence	(90,000)	—
	<u>\$ 556,620</u>	<u>\$ 1,111,507</u>

Note 6 — Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2014	December 31, 2013
Prepaid insurance	\$ 125,106	\$ 63,096
Prepaid fees and rent	249,046	151,454
Deposits and advances	1,360,672	\$ 279,870
Prepaid royalties	604,166	724,999
Other Current Assets	—	38,863
	<u>\$ 2,338,990</u>	<u>\$ 1,258,282</u>

Prepaid fees and rent consist primarily of prepaid service contracts. Deposits and advances consist primarily of payments to the Company's raw materials suppliers and Angel® centrifuge manufacturers. Other Current Assets was exclusively made up of parts used to refurbish the Angel® centrifuges. Prepaid royalties consist of a cash payment, and the fair value of the common stock and warrant issued for the release of the Worden security interest in patents (*See Note 13 - Equity for additional detail*). The royalty is amortized to cost of sales over the life of the patent. For the years ended December 31, 2014 and 2013, royalty amortization expense was approximately \$120,833 and \$100,694, respectively.

Note 7 — Property and Equipment

Property and equipment, net consisted of the following:

	December 31, 2014	December 31, 2013
Medical equipment	\$ 801,463	\$ 1,278,681
Office equipment	150,411	86,001
Software	307,844	—
Manufacturing equipment	307,851	307,971
Leasehold improvements	32,130	390,911
	<u>1,599,699</u>	<u>2,063,564</u>
Less accumulated depreciation and amortization	<u>(674,528)</u>	<u>(1,144,095)</u>
	<u>\$ 925,171</u>	<u>\$ 919,469</u>

As a result of the Arthrex Agreement (See Note 2 — Arthrex Distributor and License Agreement for additional details), Angel centrifuges were classified to “Inventory” in the accompanying consolidated balance sheets, whereas they were previously classified as “Property and equipment”.

For the year ended December 31, 2014 depreciation expense and amortization was approximately \$276,000, of which \$72,000 was reported as research, development, trials and studies, and \$105,000 was reported as cost of sales.

For the year ended December 31, 2013 depreciation expense and amortization was approximately \$726,000, of which \$299,000 was reported as research, development, trials and studies, and \$310,000 was reported as cost of sales.

The net book value of property and equipment disposed of was approximately \$265,000 in 2014 and \$1,543,000 in 2013 (which includes approximately \$1,295,000 of existing placed Angel centrifuges sold under the Arthrex Agreement). The disposal of property and equipment was primarily due to the sale of centrifuges and the close-out of our research and development facility.

Note 8 — Goodwill and Identifiable Intangible Assets

Our intangible assets consist of trademarks, technology (including patents), customer relationships, and the IPR&D. These assets are a result of the Angel Business and Aldagen acquisitions. The carrying value of our intangible assets, and the associated amortization, were as follows:

	December 31, 2014	December 31, 2013
Trademarks	\$ 1,047,000	\$ 2,310,000
Technology	2,355,000	2,355,000
Customer relationships	708,000	708,000
In-process research and development	25,926,000	29,585,000
Total	<u>\$ 30,036,000</u>	<u>\$ 34,958,000</u>
Less accumulated amortization	<u>(1,288,230)</u>	<u>(1,189,046)</u>
	<u>\$ 28,747,770</u>	<u>\$ 33,768,954</u>

As a result of our discontinuance of ALD-401 in the second quarter of 2014, we performed an assessment of our Aldagen related trademarks and IPR&D as of June 30, 2014 and determined these assets were impaired. There was no additional impairment recognized since then. At December 31, 2014 the carrying value reflects the impairment charge made to these assets.

The Company performed a quantitative assessment of our Aldagen related trademarks, and assessed changes to driving factors used in valuing that intangible asset, including the projected revenue stream, discount factor, and remaining useful life, and considered the impact of such changes to the discounted future cash flows used to value the trademarks. We concluded that the initial fair value of the Aldagen related trademarks of approximately \$1.8 million was impaired as of June 30, 2014. An impairment charge of approximately \$1.0 million was taken in the three month period ending June 30, 2014 to reflect the current fair value of approximately \$0.8 million.

The Company also performed a quantitative assessment of our IPR&D, and assessed changes to driving factors used in valuing that intangible asset, including the projected diagnostic revenue and expenses as well as the discount factor, and considered the impact of such changes to the discounted future cash flows used to value the IPR&D. We concluded that the initial fair value of the IPR&D of approximately \$29.6 million was impaired as of June 30, 2014. An impairment charge of approximately \$3.7 million was taken in the three month period ending June 30, 2014 to reflect the current fair value of approximately \$25.9 million. Our annual impairment evaluations of indefinite lived intangible assets was performed as of October 1, 2014, and it was determined that there was no additional impairment of the recorded balances. (See Note 3 — Fair Value Measurements for additional details)

We are currently conducting (i) a Phase 1/2 clinical trial in critical limb ischemia (PACE) that is being funded by the National Institutes of Health, and (ii) a Phase 1 clinical trial in grade IV malignant glioma following surgery that is funded by Duke University, both using the intellectual property and know-how encompassed by the IPR&D and trademarks. We have no current plans to change our approach with respect to these programs.

Amortization expense associated with our definite-lived intangible assets of \$157,000 was recorded to cost of royalties and approximately \$180,000 was recorded to general and administrative expense for the year ended December 31, 2014. Annual amortization expense based on our existing intangible assets and their estimated useful lives is expected to be approximately:

2015	308,400
2016	308,400
2017	308,400
2018	242,000
2019	219,900
Thereafter	1,434,800

As a result of our discontinuance of ALD-401 in the second quarter of 2014, the Company performed an impairment test of goodwill as of June 30, 2014. We also performed an impairment test of goodwill as of October 1, 2014. We perform a two-step process for measuring for impairment of goodwill. Step 1 of the impairment process is to determine if the fair value of the reporting unit exceeds its carrying value. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not impaired, thus the second step of the impairment test is unnecessary. The Company's goodwill is contained in its sole operating segment and reporting unit. Based on our assessment on June 30, 2014 and October 1, 2014, the fair value of the reporting unit, determined with reference to its quoted market cap, exceeded its carrying value at each date of assessment and the Company determined goodwill was not impaired. Accordingly, the Step Two analysis was not performed.

Note 9 — Accrued expenses

Accrued expenses consisted of the following:

	December 31, 2014	December 31, 2013
Customer deposits	2,516,202	1,795,803
Accrued compensation and benefits	984,227	795,584
Other payables	379,019	242,993
Accrued interest	1,025,623	2,250
Due to Arthrex	324,531	1,630,564
Accrued professional fees	285,446	199,634
Accrued loss on abandonment of lease, current portion	103,176	—
Accrued Angel machine refurbishment costs	600,000	—
	<u>\$ 6,218,224</u>	<u>\$ 4,666,828</u>

The amount due to Arthrex consists of payments collected on Angel sales made by Nuo Therapeutics, on behalf of Arthrex, during the transition services period (See Note 2 – Arthrex Distributor and License agreement for additional details).

Accrued interest primarily consists of the interest accrued related to the Deerfield convertible debt (See Note 11 – Debt for additional details.).

We expect to incur machine refurbishment and design improvement costs to refurbish customer placed centrifuges, therefore, an accrual of \$600,000 was established for these expected costs and is reflected in “cost of sales” on the statement of operations.

Note 10 — Deferred Revenue

Deferred revenue consists of prepaid licensing revenue from the Arthrex Agreement. Revenue related to prepaid licensing is recognized on a straight-line basis over 5 years, the term of the Arthrex Agreement. Revenue of \$402,264 and \$167,657 related to the prepaid license was recognized in the years ended December 31, 2014 and 2013, respectively. (See Note 2 — Arthrex Distributor and License Agreement for additional details.)

Note 11 — Debt

Outstanding Debt as of December 31, 2014

At December 31, 2014 we have outstanding debt consisting of the Deerfield 5.75% convertible debt due March 31, 2019.

On March 31, 2014, we executed agreements with Deerfield for the issuance of a five-year senior secured convertible credit facility. Under the terms of this agreement, Deerfield agreed to provide to us a convertible credit facility (the “Facility Agreement”) in an amount up to \$35 million which was disbursed as follows: (i) the initial draw of \$9 million of the Facility Agreement was disbursed on March 31, 2014 (the “First Draw”), and (ii) following the authorization by our shareholders to increase our authorized capital stock (the “Share Authorization Event”), which occurred on June 9, 2014, we were required to draw and Deerfield was required to fund, the remaining \$26 million of the Facility Agreement (the “Second Draw”). In addition to the convertible notes, we issued stock purchase warrants to purchase up to 97,614,999 shares of our common stock at an initial exercise price of \$0.52 per share (subject to adjustments). (See Note 13 — Equity for additional details)

Outstanding amounts under the Facility Agreement are due in full on March 31, 2019. The Facility Agreement is structured as a purchase of senior secured convertible notes (the "Notes"), which bear interest at a rate of 5.75% per annum, payable quarterly in arrears in cash or, at our election after the Second Draw, registered shares of common stock; provided, that during the first five quarters following the closing which was March 31, 2014, we have the option of having all or any portion of accrued interest added to the principal balance of the Facility Agreement. We elected to have all portions of accrued interest added to the principal balance until September 30, 2015 beginning with the interest due for third quarter of 2014.

Following the Share Authorization Event, which occurred on June 9, 2014, Deerfield has the right to convert the principal amount of the Facility Agreement into shares of our common stock ("Conversion Shares") at a per share price equal to \$0.52. In addition, we granted to Deerfield the option to require the Company to redeem up to 33.33% of the total amount drawn under the Facility Agreement together with any accrued and unpaid interest thereon, on each of the second, third, and fourth anniversaries of the closing with the option right triggered upon the Company's net revenues failing to be equal or exceed the quarterly milestone amounts set forth in the Facility Agreement. We also granted Deerfield the option to require us to apply 35% of the proceeds received by us in equity-raising transaction(s) to redeem outstanding principal and interest of the Notes, provided that the first \$10 million so raised by us will be exempt from this put option. We entered into a security agreement which provides, among other things, that our obligations under the Notes will be secured by a first priority security interest, subject to customary permitted liens, on all our assets. We also entered into a Registration Rights Agreement dated as of the same date (the "Deerfield Registration Rights Agreement") pursuant to which we agreed to file a registration statement to register the resale of the Conversion Shares and the Deerfield Warrant Shares of our common stock following the Share Authorization Event. Such Registration Rights Agreement was filed on July 10, 2014. (See Note 17 – Commitments and Contingencies for additional details regarding registration rights)

As a result of certain non-standard anti-dilution provisions and cash settlement features, we classified the detachable stock purchase warrants and the conversion option embedded in the convertible notes associated with the First Draw and Second Draw as derivative liabilities. The derivative liabilities associated with the First Draw were recorded initially at their estimated relative fair value of approximately \$6.6 million and \$3.0 million, respectively and those associated with the Second Draw, initially at their estimated relative fair value of approximately \$21.5 million and \$5.3 million respectively. As a result, we recognized a discount on the convertible notes of \$9.0 million associated with the First Draw and \$25.8 million associated with the Second Draw. We are amortizing the discount on both of the notes over the term of the notes using the effective interest method. In addition, we re-measure the warrants and the conversion option to fair value at each balance sheet date. The issuance costs, in the form of warrants and fees, related to the First Draw and Second Draw were valued at approximately \$1.5 million and \$2.6 million, respectively, were recorded as deferred debt issuance costs, and are being amortized to interest expense on a straight-line basis through the maturity date (we determined that the straight-line method of amortization did not yield a materially different amortization schedule from the effective interest method). The issuance costs associated with the Second Draw included a yield enhancement fee, for which we issued 2,709,677 shares of the Company's common stock, with a fixed value of approximately \$1.1 million which was also recorded as deferred debt issuance costs, and are being amortized to interest expense on a straight-line basis through the maturity date (we determined that the straight-line method of amortization did not yield a materially different amortization schedule from the effective interest method).

2013 Debt No Longer Outstanding at December 31, 2014

JP Nevada Trust 12% Note

On April 28, 2011, we borrowed \$2.1 million pursuant to a secured promissory note that matures May 20, 2016. The note accrued interest at a rate of 12% per annum, and required interest-only payments each quarter commencing September 30, 2011, with the then outstanding principal due on the maturity date. The note was secured by our Angel assets. In connection with the issuance of the secured promissory note, we issued the lender a warrant to purchase up to 1,000,000 shares at an exercise price of \$0.50 per share, with variable vesting provisions.

Of the \$2,100,000 due under the note, our payment obligations with respect to \$1,400,000 under the note were guaranteed by certain insiders, affiliates, and shareholders. In connection with this guarantee, we issued the guarantors warrants to purchase an aggregate of up to 1,500,000 shares, on a pro rata basis based on the amount of the guarantee, at an exercise price of \$0.50 per share with variable vesting provisions.

The warrants issued to the lender and the guarantors were valued at approximately \$546,000, were recorded as deferred debt issuance costs, and were being amortized to interest expense on a straight-line basis over the guarantee period (we determined that the straight-line method of amortization did not yield a materially different amortization schedule from the effective interest method).

On March 31, 2014 in connection with the Deerfield Facility, JP Nevada Trust agreed to subordinate its security interest in the note. In consideration, we issued to the holder a 5-year warrant to purchase 750,000 shares of our common stock at an exercise price of \$0.52 per share. The warrants were valued at approximately \$14,000 and are classified as derivative liabilities.

The \$2.1 million note with JP Nevada Trust was retired in conjunction with the Second Draw under the Facility Agreement in June 2014 and the warrants expired pursuant to their terms upon repayment of the debt. The corresponding deferred debt issuance costs of \$298,000 were charged to interest expense in the consolidated statements of operations and we re-measured the corresponding warrants to fair value at June 30, 2014. (See Note 13 – Equity for additional details)

JMJ 4% Convertible Notes

On July 15, 2011, we issued \$1.3 million of our 4% Convertible Notes (the “July 4% Convertible Notes”) to JMJ Financial. The July 4% Convertible Notes were scheduled to mature on May 23, 2016 and included a one-time interest charge of 4% due on maturity. The July 4% Convertible Notes (plus accrued interest) converted at the option of the holder, in whole or in part and from time to time, into shares of our common stock at a conversion rate equal to (i) the lesser of \$0.80 per share or (ii) 80% of the average of the three lowest closing prices of our common stock for the previous 20 trading days prior to conversion (subject to a “floor” price of \$0.25 per share). On April 28, 2014, the remaining balance of the face amount of the July 4% Convertible Notes and accrued interest were converted into approximately 347,000 shares of common stock at a conversion price of \$0.41 per share.

Mid-Cap Financial Term Loan

On February 19, 2013, we entered into a Credit and Security Agreement (the “Credit Agreement”) with Mid-Cap Financial (“MidCap”) that provided for aggregate term loan commitments of \$7.5 million, subsequently modified to \$4.5 million. We received the first tranche of \$4.5 million on February 27, 2013. On March 31, 2014, we repaid the term loan in its entirety along with approximately \$330,000 in early payment penalties and fees. The balance of the unamortized debt discount of approximately \$381,000 and deferred fees of approximately \$142,000 were charged to interest expense in the consolidated statements of operations.

In connection with term loan, we issued the lender a seven-year warrant to purchase 1,079,137 shares of the Company’s Common stock at the warrant exercise price of \$0.70 per share. The exercise price and the number of shares issuable upon exercise of the warrant is subject to standard anti-dilution adjustments and contains a cashless exercise provision. The warrants issued to the lender were valued at approximately \$568,000, were recorded as a debt discount, and were being amortized to interest expense over the term of the loan (we determined that the straight-line method of amortization did not yield a materially different amortization schedule from the effective interest method). The warrants are classified in equity.

On December 10, 2013, we revised the exercise price of the warrants to \$0.46 per share (“Amendment to the MidCap Warrant”). As a result of the Amendment to the MidCap Warrant, the fair value of the warrants were modified and the change was recognized as an increase to debt discount and amortized over the remaining life of the loan. The change in the fair value of the warrants was approximately \$12,000.

December 2013 Convertible Bridge Note

On November 21, 2013, we executed agreements with certain investors for the subsequent issuance of 10% subordinated convertible notes ("10% Subordinated Convertible Notes") and stock purchase warrants, for gross proceeds of up to \$3 million. The eventual closing was contingent upon several factors; we received \$2.25 million of the expected gross proceeds at the first closing, which occurred on December 10, 2013 after the Company received an acceptable Centers for Medicare and Medicaid Services ("CMS") reimbursement determination for Aurix™. We received \$0.75 million of the gross proceeds in February 2014.

On March 31, 2014 the holders of the December 2013 convertible bridge notes (except for one holder), agreed to convert their outstanding notes pursuant to its terms, converting into 5,981,859 shares of common stock. The Company repaid, in its entirety, the portion of the debt excluded from the conversion (including interest and prepayment penalties) pursuant to its terms, for a total cash payment of approximately \$339,000. The unamortized balance of the related debt discount, deferred fees, and derivative liability for the embedded conversion feature, were reclassified to additional paid-in capital.

The conversion option embedded in the 10% Subordinated Convertible Notes and related warrants issued to the investors was accounted for as a derivative liability and was recorded at full fair value relative to the total gross proceeds which totaled \$2.25 million at December 10, 2013, resulting in a debt discount of \$2.25 million. The debt discount was amortized as additional interest expense using the interest rate method through the maturity date. The embedded conversion option and the warrants were recorded at fair value and marked to market at each period, with the resulting change in fair value reflected as "change in fair value of derivative liabilities" in the accompanying consolidated statements of operations.

In connection with the issuance of the Notes, we also agreed to issue to the investors in the Offering five-year warrants (the "Warrants") to purchase shares of our Common stock in the amount equal to 75% of the number of shares into which the Notes may be converted at the Closing, at an exercise price equal to 125% of the Market Price (as defined). The Warrants also contain non-standard anti-dilution adjustments and contain certain net settlement features.

Warrants issued to the placement agent were valued at approximately \$69,000, were recorded as deferred debt issuance costs, and were being amortized to interest expense on a straight-line basis through the maturity date (we determined that the straight-line method of amortization did not yield a materially different amortization schedule from the effective interest method).

As a result of the scheduled expiration of non-standard anti-dilution clauses contained within the investors and placement agent warrants, the warrants were reclassified to equity at their fair value on June 9, 2014.

Note 12 — Income Taxes

Income tax (expense) benefit for the years ended December 31, 2014 and 2013 consisted of the following:

	<u>2014</u>	<u>2013</u>
Current:		
Federal	\$ —	\$ —
State	—	—
Deferred:		
Federal	9,513,282	(212,022)
State	952,533	(401,215)
Net operating loss carryforward	7,764,117	4,243,885
Valuation Allowance	(18,249,516)	(3,649,237)
Total income tax (expense) benefit	<u>\$ (19,584)</u>	<u>\$ (18,589)</u>

Significant components of Nuo Therapeutics' deferred tax assets and liabilities consisted of the following at December 31:

	2014	2013
Deferred tax assets:		
Stock-based compensation	\$ 5,942,000	\$ 5,371,000
Tax credits	3,162,000	2,895,000
Deferred revenue	575,000	861,000
Start-up and organizational costs	276,000	272,000
Tax deductible Goodwill	88,000	112,000
Property and equipment	56,000	240,000
Other	389,000	153,000
Total deferred tax assets	<u>10,488,000</u>	<u>9,904,000</u>
Deferred tax liabilities:		
Intangible Assets	(10,325,000)	(12,219,000)
Discount on Note Payable	(13,825,000)	(1,088,000)
Other	(89,000)	(69,000)
Total deferred tax liabilities	<u>(24,239,000)</u>	<u>(13,376,000)</u>
Net deferred tax assets, excluding net operating loss carryforwards	(13,751,000)	(3,472,000)
Net operating loss carryforwards	53,222,000	45,458,000
	<u>39,471,000</u>	<u>41,986,000</u>
Less valuation allowance	(39,559,000)	(42,055,000)
Total deferred tax assets (liabilities)	<u>\$ (88,000)</u>	<u>\$ (69,000)</u>

The following table reflects the change in the valuation allowance for deferred tax assets at December 31:

Valuation allowance - January 1, 2013	\$ 38,406,000
2013 provision	<u>3,649,000</u>
Valuation allowance - December 31, 2013	\$ 42,055,000
Establishment and reversal in 2014 - Convertible Bridge notes	897,000
Establishment in 2014 - Deerfield note	(13,878,000)
2014 provision	<u>10,485,000</u>
Valuation allowance - December 31, 2014	\$ <u>39,559,000</u>

The following table presents a reconciliation between the U.S. federal statutory income tax rate and the Company's effective tax rate:

	2014	2013
U.S. Federal statutory income tax	35.0%	35.0%
State and local income tax, net of benefits	4.9%	4.4%
Fair value of Derivatives	17.1%	(2.9)%
Nondeductible guarantee fees	—	(0.9)%
Impact of changes in rates	(0.2)%	(12.2)%
Established/reversed tax deferrals (deferred tax liabilities) not thru provision	(68.8)%	(5.5)%
Other	(1.3)%	—
Valuation allowance for deferred income tax assets	13.2%	(18.0)%
Effective income tax rate	<u>(0.1)%</u>	<u>(0.1)%</u>

The Company had loss carry-forwards of approximately \$142,701,000 as of December 31, 2014 that may be offset against future taxable income. The carry-forwards will expire between 2021 and 2034. Use of these carry-forwards may be subject to annual limitations based upon previous significant changes in stock ownership. Management has determined that realization of the net deferred tax assets is not assured and accordingly has established a valuation allowance of \$39,559,000 and \$42,055,000 at December 31, 2014 and 2013, respectively.

In 2014 and 2013, the Company recorded an income tax provision of approximately \$20,000 and \$19,000, respectively, related to a deferred tax liability resulting from the amortization of Goodwill for tax purposes. No income tax benefit was recognized in the consolidated statements of operations for stock-based compensation for the years presented due to the Company's net loss position.

The Company's source of income (loss) before income tax provision (benefit) is from both U.S. and foreign sources.

The Company does not believe it has any uncertain income tax positions as described in its discussion of Income Tax accounting policy in Note 1 – Business and Presentation.

Note 13 — Equity

Common Stock

Our common stock has a par value of \$.0001 per share. On June 9, 2014, the Company's shareholders approved an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of all classes of capital stock from 215,000,000 shares to 440,000,000 shares, and the authorized number of common stock from 200,000,000 shares to 425,000,000 shares. Common stock is subordinate to Series A, B, C, and D Convertible Preferred stock. Each share of common stock represents the right to one vote, and common stockholders are entitled to receive dividends as may be declared by the Board of Directors. No dividends were declared or paid on our common stock in 2014 and 2013.

2014 Private Placement. In March 2014 we raised \$2.0 million from the private placement of 3,846,154 shares of common stock (at a price of \$0.52 per share) and five-year stock purchase warrants to purchase 2,884,615 shares of common stock at \$0.52 per share. As a result of certain non-standard anti-dilution provisions and cash settlement features contained in the warrants, we classified the detachable stock purchase warrants as derivative liabilities, initially at their estimated relative fair value of approximately \$1.1 million. We re-measure the warrants to fair value at each balance sheet date. Issuance costs, in the form of warrants and fees, were valued at approximately \$136,000 and were recorded to additional paid-in-capital.

2014 Issuance to Deerfield. In June 2014, we issued 2,709,677 shares of our common stock (with a value of \$1.1 million) to Deerfield in satisfaction of certain transaction fees.

2014 Issuance to former Aldagen Shareholders. In November 2014, we amended and settled our contingent consideration obligations from our 2012 acquisition of Aldagen by issuing 1,270,000 shares of our common stock.

2014 and 2013 Issuances to Lincoln Park. In February 2013, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Under the terms and subject to the conditions of the agreements, the Company has the right to sell to and Lincoln Park is obligated to purchase up to \$15 million in shares of the Company's common stock, subject to certain limitations, from time to time, over the 30-month period commencing on the date that a registration statement is declared effective by the SEC. The Company may direct Lincoln Park every other business day, at its sole discretion and subject to certain conditions, to purchase up to 150,000 shares of common stock in regular purchases, increasing to amounts of up to 200,000 shares depending upon the closing sale price of the common stock. In addition, the Company may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below \$1.00 per share. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold under this arrangement on a day the common stock closing price is less than the floor price of \$0.45 per share, subject to adjustment. The Company's sales of shares of common stock under the agreements are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the Common Stock.

To date, we have issued 5,250,000 shares to Lincoln Park (raising approximately \$2.4 million in gross proceeds) with up to 4,750,000 shares or \$12.6 million in shares still available for issuance under this arrangement. In addition to those shares, the Company issued to Lincoln Park 375,000 shares of common stock, and is required to issue up to 375,000 additional shares of common stock, in satisfaction of certain transaction fees. To date we have issued 59,126 shares of common stock in satisfaction of those certain transaction fees. This arrangement expires January 17, 2015.

2013 Public Offering. In February 2013, the Company issued 9,090,911 shares of the common stock and five-year stock purchase warrants to purchase an additional 6,363,638 shares of common stock (raising \$5.0 million or gross proceeds). The purchase price paid by investors was \$0.55 for each unit. Each warrant is immediately exercisable at \$0.75 per share on or after February 22, 2013 and is subject to transfer restrictions, including among others, compliance with the state securities laws. The warrants are classified in equity.

In connection with the offering, the Company and the Maryland Venture Fund (Maryland Department of Business and Economic Development) executed an agreement which requires the Company to repurchase MVF's investment, at MVF's option, upon certain events outside of the Company's control. The common stock issued to MVF is classified as "contingently redeemable common shares" in the accompanying consolidated balance sheets.

The Company paid \$402,000 in cash transaction fees to its placement agent, and granted to the placement agent stock purchase warrants to purchase 136,364 shares of common stock. The warrants have the same terms as the investor warrants in this offering, except that the exercise price will be 120% of the exercise price of the investor warrants and may also be exercised on a cashless basis. We also provided the purchasers certain registrations rights.

2013 Release of the Worden Security Interest in the Licensed Patents. In February 2013, the Company and Charles E. Worden Sr., an individual holder of security interest in patents pursuant to the Substitute Royalty Agreement, dated November 4, 2001 amended that agreement (the "SRA Amendment") for the purposes of terminating and releasing the security interest and the reversionary interest under the terms of the SRA in exchange for the following consideration: (i) a one-time cash payment of \$500,000 (to replace all future minimum monthly royalty payments), (ii) issuance of 250,000 shares of the Company's common stock (the "Worden Shares"), and (iii) grant of the right to acquire up to 250,000 shares of the Company's common stock pursuant to a seven-year stock purchase warrant with the exercise price of \$0.70 per share. In addition, Mr. Worden's future annual royalty stream limitation was increased from \$600,000 to \$625,000. The exercise price and the number of shares issuable upon exercise of the warrant is subject to standard anti-dilution provisions, and contain provisions that are customary for the instruments of this nature, including, among others, a cashless exercise provision. The warrants are classified as equity.

2013 JP Nevada Trust Note Amendment. In February 2013, the Company amended its note with JP's Nevada Trust (the "JP Trust Note") to subordinate the lender's security interest under the JP Trust Note to that of MidCap. In exchange the Company agreed to (i) extend the maturity date of the JP Trust Note to November 19, 2016 and (ii) expand the lender's second lien security interest to include the assets of the Company and Aldagen. The parties also agreed to amend the vesting schedule on the lender's warrants such that the remaining 250,000 warrant shares are exercisable immediately. Finally, the Company agreed to issue the lender a new warrant to purchase up to 266,666 shares at an exercise price of \$0.70 per share vesting as follows: (i) 133,333 shares may be exercised only if the JP Trust Note has not been paid by the fourth anniversary of its issuance, and (ii) the remaining 133,333 shares may be exercised only if the JP Trust Note has not been paid by the fifth anniversary of its issuance.

The Company's payment obligations with respect to \$1.4 million of the JP Trust Note were guaranteed by certain insiders, affiliates, and shareholders of the Company, including David E. Jordan, then Chairman of the Board (the "Guarantors"). In connection with the JP Trust Note amendment, the Company also: (i) approved amendments to the warrant vesting schedule on the Guarantors' warrants (including those held by Mr. Jordan) issued by the Company in April 2011 such that the remaining 500,000 warrant shares are exercisable immediately and (ii) granted the right to the Guarantors to acquire up to 533,334 shares of the Company's common stock pursuant to warrants at the exercise price of \$0.70 per share, vesting as follows: (i) 266,667 warrant shares may be exercised only if the JP Trust Note has not been prepaid by the fourth anniversary of its issuance, and (ii) the remaining 266,667 shares may be exercised only if the JP Trust Note has not been paid by the fifth anniversary of its issuance (including 107,143 of the previously issued warrants held by Mr. Jordan, which will now vest immediately, and (i) 57,143 of his warrant shares may be exercised only if the JP Trust Note has not been paid by the fourth anniversary of its issuance, and (ii) the remaining 57,143 shares may be exercised only if the JP Trust Note has not been paid by the fifth anniversary of its issuance).

2013 JMJ Financial Note Amendment and Subordination. In February 2013, the Company amended its notes with JMJ Financial (the "JMJ Notes"), to subordinate JMJ's rights and remedies under the JMJ Note to that of MidCap. In exchange, the Company extended the maturity date of the JMJ Notes to the later of (i) three years from the effective date of such notes or (ii) the date that is one business day following the date the MidCap loan is paid in full. In addition, JMJ converted \$100,000 of the outstanding balance on one of the JMJ Notes into shares of the Company's common stock and the Company remitted a payment in the amount of \$370,000 to partially satisfy one of the JMJ Notes.

Stock Purchase Warrants

The Company had the following stock purchase warrants outstanding at December 31:

Outstanding		Exercise Price	Expiration	Classification
12/31/14	12/31/13			
-	200,000	\$ 1.50	February-14	Equity
-	800,000	\$ 0.70	June-14	Equity
-	1,180,547	\$ 1.42	December-14	Equity
-	2,115,596	\$ 1.42	December-14	Equity
1,070,916	1,070,916	\$ 0.51	February-15	Equity
325,000	325,000	\$ 1.25	February-15	Equity
325,000	325,000	\$ 1.50	February-15	Equity
325,000	325,000	\$ 1.75	February-15	Equity
1,295,138	1,295,138	\$ 0.54	April-15	Equity
100,000	100,000	\$ 0.37	October-15	Equity
1,488,839	1,488,839	\$ 0.60	April-16	Equity
916,665	916,665	\$ 0.50	April-16	Equity
20,000	-	\$ 0.40	June-16	Equity
136,364	136,364	\$ 0.66	February-18	Equity
6,363,638	6,363,638	\$ 0.75	February-18	Equity
5,047,461	5,047,461	\$ 0.65	December-18	Equity*
232,964	-	\$ 0.65	December-18	Equity
2,884,615	-	\$ 0.52	March-19	Liability
1,474,615	-	\$ 0.52	March-19	Liability
3,525,000	-	\$ 0.52	June-19	Liability
1,079,137	1,079,137	\$ 0.70	February-20	Equity
250,000	250,000	\$ 0.70	February-20	Equity
25,115,384	-	\$ 0.52	March-21	Liability
67,500,000	-	\$ 0.52	June-21	Liability
119,475,736	23,019,301			

* These warrants were reclassified to additional paid-in capital as a result of the expiration of non-standard anti-dilution clauses contained within the warrants.

Certain of the above warrants were issued to consultants in exchange for services provided (see "stock-based compensation" below).

Stock -Based Compensation

The Company's 2002 Long Term Incentive Plan ("LTIP") and 2013 Equity Incentive Plan ("EIP" and, together with the LTIP, the "Plans") permit the awards of stock options, stock appreciation rights, restricted stock, phantom stock, performance units, dividend equivalents and other stock-based awards to employees, directors and consultants. We are authorized to issue up to 10,500,000 shares of common stock under the LTIP and up to 18,000,000 shares under the EIP (as approved by our shareholders on June 9, 2014). At December 31, 2014, 2,416,721 and 11,345,852 shares were available to be issued under the LTIP and EIP, respectively.

To date, the Company has only issued stock options under the Plans. Stock option terms are determined by the Board of Directors for each option grant, and generally vest immediately upon grant or over a period of time ranging up to four years, are exercisable in whole or installments, and expire no longer than ten years from the date of grant. A summary of stock option activity under the Plans as of December 31, 2014, and changes during 2014, is presented below:

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2014	8,520,816	\$ 1.19		
Granted	8,462,248	\$ 0.55		
Exercised	0	—		
Forfeited or expired	(2,777,439)	\$ 1.25		
Outstanding at December 31, 2014	14,205,625	\$ 0.80	7.2	\$ 2,000
Exercisable at December 31, 2014	7,298,305	\$ 1.05	5.3	\$ 2,000

The weighted-average grant-date fair value of stock options granted under the Plans during 2014 and 2013 was \$0.40 and \$0.45, respectively. We granted 8,462,248 and 1,038,000 stock options during 2014 and 2013, respectively; the fair value of stock options granted and vested during 2014 and 2013 was approximately \$1,037,000 and \$712,000, respectively. No stock options were exercised during 2014 and 2013. As of December 31, 2014, there was approximately \$2,400,000 of total unrecognized compensation cost related to non-vested stock options, and that cost is expected to be recognized over a weighted-average period of 2.9 years. The following table summarizes information about stock options outstanding as of December 31, 2014:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Outstanding Shares	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.30 - \$0.50	3,049,748	8.11	\$ 0.41	954,164	\$ 0.43
\$0.51 - \$0.75	7,721,900	8.40	\$ 0.60	2,932,999	\$ 0.60
\$0.76 - \$1.25	805,000	5.40	\$ 0.95	805,000	\$ 0.95
\$1.26 - \$1.75	1,733,477	3.91	\$ 1.42	1,732,477	\$ 1.42
\$1.76 - \$2.75	825,500	2.42	\$ 2.32	803,665	\$ 2.32
\$2.76 - \$4.50	0	0.00	—	0	—
\$4.51 - \$6.00	70,000	1.03	\$ 5.20	70,000	\$ 5.20

Additionally, the Company has issued certain stock purchase warrants in exchange for the performance of services, not covered by the Plans. A summary of service provider warrant activity as of December 31, 2014, and changes during 2014, is presented below:

Warrants to Service Providers	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2014	1,661,364	\$ 1.24	1.9	
Granted	20,000	\$ 0.40		
Exercised	0	—		
Forfeited or expired	(200,000)	\$ 1.50		
Outstanding at December 31, 2014	1,481,364	\$ 1.20	1.3	\$ 0
Exercisable at December 31, 2014	1,471,364	\$ 1.20	1.3	\$ 0

There were 486,364 such warrants granted in 2013, and there were no exercises in 2013. The following table summarizes information about these warrants outstanding as of December 31, 2014:

Range of Exercise Prices	Warrants Outstanding			Warrants Exercisable	
	Number of Outstanding Shares	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.30 - \$0.50	120,000	0.9	\$ 0.38	110,000	\$ 0.37
\$0.51 - \$0.75	386,364	4.4	\$ 0.69	386,364	\$ 0.69
\$0.76 - \$1.25	325,000	0.1	\$ 1.25	325,000	\$ 1.25
\$1.26 - \$1.75	650,000	0.1	\$ 1.63	650,000	\$ 1.63

As of December 31, 2014, there was approximately \$1,000 of total unrecognized compensation cost related to these warrants, which is expected to be recognized over a weighted-average period of 0.5 years.

The Company has recorded stock-based compensation expense as follows:

Stock-Based Expense	Year Ended December 31	
	2014	2013
Awards under the 2002 LTIP and 2013 EIP	1,269,150	679,550
Awards outside the equity-based plans	10,145	38,313
	<u>\$ 1,279,295</u>	<u>\$ 717,863</u>
Included in Statements of Operations caption as follows:		
Salaries and wages	\$ 1,154,767	\$ 564,737
Consulting expense	10,145	16,278
General and administrative	114,383	136,848
	<u>\$ 1,279,295</u>	<u>\$ 717,863</u>

Note 14 — Supplemental Cash Flow Disclosures — Non-Cash Transactions

Non-cash Investing and Financing transactions for years ended December 31 include:

	2014	2013
Conversion of convertible debt to common stock	\$ 3,067,423	\$ 523,927
Reclassification of the unamortized balance of debt discount and derivative liability, related to the extinguishment and conversion of the subordinated convertible debt, to additional paid-in capital	2,860,627	—
Derivative liability created from conversion option embedded in Deerfield convertible credit facility	8,825,935	—
Effect of modification of convertible debt	—	151,032
Common Stock issued for committed equity financing facility	—	204,015
Warrants issued for term loan modification	—	151,758
Warrants issued for term loan	—	568,324
Common stock and warrants issued for release of security interest in patents	—	325,693
Warrants issued in connection with convertible debt and equity facility	29,137,682	1,353,842
Derivative liability for embedded conversion option	—	965,484
Common stock issued for professional services	—	17,850
Common stock issued for settlement of contingency	39,150	39,150
Reclassification of warrant derivative liability to additional paid-in capital as a result of the expiration of non-standard anti-dilution clause contained in warrants	1,331,776	—
Issuance of common stock in connection with convertible debt facility	1,050,000	—
Common stock issued to satisfy contingent consideration	127	—
Accrued property and equipment	64,108	—

Cash paid for interest was \$379,000 and \$564,000 in 2014 and 2013, respectively. There were no income taxes paid in 2014 and 2013.

Note 15 — Operating Leases

The Company leases its office spaces under operating leases with approximate future minimum lease payments as indicated in the table below:

Years ending December 31:	
2015	\$ 439,000
2016	451,000
2017	463,000
2018	441,000
2019	122,000
Thereafter	—
Total future minimum lease payments	<u>\$ 1,916,000</u>

Our primary office and warehouse facilities are located in Gaithersburg, Maryland, and comprise approximately 12,000 square feet. The facilities fall under two leases with monthly rent, including our share of certain annual operating costs and taxes, at approximately \$13,000 and \$4,000 per month with the leases expiring September 2019. In addition, we lease a 2,076 square foot facility in Nashville, Tennessee which is being utilized as a commercial operations. The lease is approximately \$4,000 per month excluding our shares of annual operating expenses and expires April 30, 2018. We also lease a 16,300 square foot facility located in Durham, North Carolina. This facility falls under one lease with monthly rent, including our share of certain annual operating costs and taxes, at approximately \$20,000 per month with the lease expiring December 31, 2018. As a result of our discontinuance of the ALD-401 clinical trial, the Company ceased use of the facility in Durham, North Carolina on July 31, 2014 and sublet the facility beginning August 1, 2014. The sublease rent is approximately \$13,000 per month and expires December 31, 2018.

For the years ended December 31, 2014 and 2013, the Company incurred rent expense of approximately \$515,000 and \$324,000, respectively. In 2014 we recorded rent expense of approximately \$242,000 for a loss on the abandonment of lease as a result of our discontinued use and following sublet of the Durham, North Carolina facility.

Note 16 — Geographic Concentration Information

Product sales consist of the following:

	Year Ended December 31,	
	2014	2013
Revenue from U.S. product sales	\$ 4,273,181	\$ 9,549,015
Revenue from non-U.S. product sales	1,576,149	949,711
Total revenue from product sales	<u>\$ 5,849,330</u>	<u>\$ 10,498,726</u>

Note 17 — Commitments and Contingencies

Series A Preferred stock contingency

Under the Company's plan of reorganization upon emergence from bankruptcy in July 2002, the Series A Preferred stock and the dividends accrued thereon that existed prior to emergence from bankruptcy were to be exchanged into one share of new common stock for every five shares of Series A Preferred stock held as of the date of emergence from bankruptcy. This exchange was contingent on the Company's attaining aggregate gross revenues for four consecutive quarters of at least \$10,000,000 and if met would result in the issuance of 325,000 shares of the Company's common stock. The Company reached such aggregate revenue levels as of the end of the quarter ended June 30, 2012. As of December 31, 2014, 271,000 common stock issuable remain.

Aldagen Contingent Consideration

Aldagen's former investors had the right to receive up to 20,309,723 shares of our common stock, contingent upon the achievement of certain milestones related to the current ALD-401 Phase 2 clinical trial.

Under the terms of the February 2013 amendment to the Exchange and Purchase Agreement by and among Nuo Therapeutics, Inc., Aldagen, Inc. and Aldagen Holdings, LLC, the parties to the agreement modified the terms of the post-closing contingent consideration under the terms of the original agreement. Following and as a result of the amendment, Nuo Therapeutics recognized approximately \$1,006,000 as operating expense with the offset to equity for the period ended December 31, 2013.

On November 11, 2014, the Company and Aldagen Holdings, LLC, executed that certain Second Amendment to the February 8, 2012 Exchange and Purchase Agreement, as amended on February 8, 2013 (as amended to date, the "Exchange Agreement"). Pursuant to the terms of the Second Amendment, the terms of the post-closing consideration originally contemplated under the Exchange Agreement and structured around the achievement of certain milestone events relating to the Company's ALD-401 Phase 2 clinical trials were amended such that, in full satisfaction of all the post-closing issuance obligations of the Company to Aldagen Holdings, the Company agreed to a one-time issuance of 1,270,000 shares of Nuo Therapeutics common stock, out of the 20,309,723 shares of our common stock held in reserve, which were contingently issuable upon the achievement of certain milestones related to the current ALD-401 Phase 2 clinical trial.

Deerfield Registration Rights Agreement

On March 31, 2014, we entered into a Registration Rights Agreement (the "RRA") with Deerfield investors pursuant to the terms and provisions of the March 31, 2014 Facility Agreement and agreed to register, among others, shares of our common stock issuable upon conversion and exercise of convertible notes and related common stock warrants sold in the March 31 and June 30 Deerfield financings. At the time of the closing of the March 31st draw, we issued to Deerfield warrants to purchase 25,115,384 shares of the Company's common stock at an exercise price of \$0.52 per share; at the time of the June 25th draw - warrants to purchase 67,500,000 shares of the Company's common stock at an exercise price of \$0.52 per share. The maximum number of shares of our common stock that can be issued pursuant to the conversion of the Deerfield facility is 67,307,692 shares; the maximum number of shares of our common stock that can be issued pursuant to the terms of the Deerfield warrants is 92,615,385 shares. In accordance with the RRA, we are obligated to file and maintain an effective registration statement, all in accordance with the terms of the RRA until the date when all shares underlying the convertible notes and related warrants (and any other securities issued or issuable with respect to in exchange for such shares) have been sold or at any time following the six month anniversary of the date of issuance, all warrant shares issuable upon exercise of the warrants should be eligible for immediate resale pursuant to Rule 144 under the Securities Act.

FDA clearance

In conjunction with its FDA clearance, we agreed to conduct a post-market surveillance study to further analyze the safety profile of bovine thrombin as used in the Aurix™ System. This study was estimated to cost between \$500,000 and \$700,000 over a period of several years, which began in the third quarter of 2008. As of December 31, 2014, approximately \$368,000 had been incurred. Since the inception of this study, we have enrolled 120 patients, noting no adverse events. Based on the additional positive safety data, we suspended further enrollment in this study pending further discussion with the FDA.

Letter of Credit

In July 2009, in satisfaction of a Maryland law pertaining to Wholesale Distributor Permits, we established a Letter of Credit, in the amount of \$50,000, naming the Maryland Board of Pharmacy as the beneficiary. This Letter of Credit serves as security for the performance by the Company of its obligations under applicable Maryland law regarding this permit and is collateralized by a Certificate of Deposit ("CD") purchased from our commercial bank. This CD bears interest at an annual rate of 0.10% and matures on June 24, 2015.

MVF Stock Repurchase Agreement

The Company and the MVF, in compliance with MVF's investment policies, agreed to execute a certain Stock Repurchase Agreement which requires us to repurchase the MVF's investment, at MVF's option, upon certain events outside of our control; provided, however, that in the event that, at the time of either such event our securities are listed on a national securities exchange, the foregoing repurchase will not be triggered. The common shares issued to MVF are classified as "conditionally redeemable common stock" in the accompanying consolidated balance sheet. The value of the warrants and offering expenses allocable to the contingently redeemable common shares was not material. Upon the termination of the stock repurchase agreement or the sale of the stock by MVF, the temporary equity will be re-classified to permanent equity.

Note 18 — Subsequent Events

In September 2009, we entered into a license and distribution agreement with Millennia Holdings, Inc. ("Millennia") for the Company's Aurix System in Japan. Since then, Millennia has been collecting and publishing clinical data for regulatory purposes and expanding the utilization of Aurix throughout their network. The diabetic population in Japan is estimated to be approximately seven million adults. Millennia has assisted the Company in securing a partner to address widespread distribution in Japan. In January 2015 we granted to Rohto Pharmaceutical Co., Ltd. ("Rohto") a royalty bearing, nontransferable, exclusive license, with limited right to sublicense, to use certain of the Company's intellectual property for the development, import, use, manufacturing, marketing, sale and distribution for all wound care and topical dermatology applications of the Aurix system and related intellectual property and know-how in human and veterinary medicine in Japan in exchange for an upfront payment from Rohto of \$3.0 million (which is reduced by the \$1.5 million payment to Millennia Holdings, as set forth below). The agreement also contemplates additional royalty payments based on the net sales of Aurix in Japan and an additional future cash payment in the event specific milestones are met. In connection with and effective as of the entering into the Rohto Agreement, we executed Amendment No. 5 to the Licensing and Distribution Agreement with Millennia dated September 10, 2009, as subsequently amended to terminate the Millennia Agreement and to allow us to transfer the exclusivity rights from Millennia to Rohto. In connection with this amendment we paid a one-time, non-refundable fee of \$1.5 million to Millennia upon our receipt of the \$3.0 million upfront payment from Rohto and may be required to pay certain future royalty payments to Millennia based upon net sales in Japan. Millennia has been instrumental in establishing the advanced wound care market in Japan, and will continue to work with Rohto to develop the market for Aurix. Further, Rohto has assumed all responsibility for securing the Marketing Authorization ("MA") from Japan's Ministry of Health, Labour and Welfare ("MHLW"), while

we will provide relevant product information, as well as clinical and other data to support Rohto's MA application.

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 Annual Report, under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer (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) of 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 Commission’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 Officers, to allow timely decisions regarding required disclosure. Based on this evaluation, the Certifying Officers have concluded that the Company’s disclosure controls and procedures were effective as of December 31, 2014.

Management’s Report on Internal Control over Financial Reporting

The Company’s management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of its management, including the Certifying Officers, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in the 2013 *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The Company’s internal control over financial reporting is a process designed 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 in the United States of America. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

Based on this evaluation under the framework in the 2013 *Internal Control — Integrated Framework*, management concluded that the Company’s internal control over financial reporting was effective as of December 31, 2014.

Changes in Internal Control over Financial Reporting

There was no changes in our internal control over financial reporting during the most recently completed quarter that has materially affected, or is 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

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

ITEM 11. Executive Compensation

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

ITEM 14. Principal Accounting Fees and Services

The information required by this Item is incorporated by reference to our definitive proxy statement or an amendment to our Annual Report on Form 10-K to be filed within 120 days of our fiscal year end.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules

(a) The following financial statements of Nuo Therapeutics are included in Item 8 of Part II of this Annual Report on Form 10-K:

	Page
Report of Independent Registered Public Accounting Firm	47
Consolidated Balance Sheets	48
Consolidated Statements of Operations	49
Consolidated Statements of Redeemable Common Stock and Stockholders' Equity	50
Consolidated Statements of Cash Flows	52
Notes to Consolidated Financial Statements	53

(b) For a list of exhibits filed or furnished with this Annual Report on Form 10-K, see Exhibit Index.

(c) Not applicable.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NUO THERAPEUTICS, INC.

Date: March 31, 2015

By: */s/ Martin P. Rosendale*
Martin P. Rosendale
Chief Executive Officer and Director
(Principal Executive Officer)

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 31, 2015

/s/ Martin P. Rosendale
Martin P. Rosendale
Chief Executive Officer and Director
(Principal Executive Officer)

Date: March 31, 2015

/s/ Steven A. Shallcross
Steven A. Shallcross
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 31, 2015

/s/ David E. Jorden
David E. Jorden
Executive Chairman of the Board

Date: March 31, 2015

/s/ Stephen N. Keith
Stephen N. Keith
Director

Date: March 31, 2015

/s/ Mark T. McLoughlin
Mark T. McLoughlin
Director

Date: March 31, 2015

/s/ C. Eric Winzer
C. Eric Winzer
Director

Date: March 31, 2015

/s/ Lyle Hohnke
Lyle Hohnke
Director

Date: March 31, 2015

/s/ Joseph Del Guercio
Joseph Del Guercio
Director

Signed originals of this written statement have been provided to Nuo Therapeutics and will be retained by Nuo Therapeutics and furnished to the SEC or its staff upon request.

EXHIBIT INDEX

Number	Exhibit Table
2.1	First Amended Plan of Reorganization with All Technical Amendments (previously filed on June 28, 2002, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).
2.2	Amended and Restated Official Exhibits to the First Amended Plan of Reorganization of Cytomedix with All Technical Amendments (previously filed on May 10, 2004, as exhibit to Form 10-QSB for the quarter ended March 31, 2004, File No. 000-28443, and incorporated by reference herein).
2.3	Asset Purchase Agreement by and among Sorin, Cytomedix Acquisition Company and Cytomedix, dated as of April 9, 2010 (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
2.4	Exchange Amendment by and among, Cytomedix, Aldagen, Inc., a Delaware corporation and Aldagen Holdings, a North Carolina limited liability company, dated February 8, 2012 (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
3(i)	Restated Certificate of Incorporation of Cytomedix (previously filed on November 7, 2002, as exhibit to Form 10-QSB for quarter ended June 30, 2001, File No. 000-28443, and incorporated by reference herein).
3(i)(iii)	Certificate of Amendment to the Certificate of Incorporation (previously filed on June 6, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
3(i)(1)	Amendment to Restated Certificate of Incorporation of Cytomedix (previously filed on November 15, 2004, as exhibit to Form 10-QSB for quarter ended September 30, 2004, File No. 000-28443, and incorporated by reference herein).
3(i)(2)	Certificate of Amendment to the Certificate of Incorporation (previously filed on July 1, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
3(i)(3)	Certificate of Amendment to the Certificate of Incorporation, as amended (previously filed on June 13, 2014 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference).
3(ii)	Restated Bylaws of Cytomedix (previously filed on November 7, 2002, as exhibit to Form 10-QSB for quarter ended June 30, 2001, File No. 000-28443, and incorporated by reference herein).
4.1	Amended and Restated Certificate of Designation of the Relative Rights and Preferences of Series A Preferred, Series B Preferred and Common stock of Cytomedix (previously filed on March 31, 2004, as exhibit to Form 10-KSB for year ended December 31, 2003, File No. 000-28443, and incorporated by reference herein).
4.2	Form of Class A Warrant issued to New Investors and DIP Lenders (previously filed on December 5, 2002, as exhibit to Form 10-QSB for quarter ended September 30, 2001, File No. 000-28443, and incorporated by reference herein).
4.3	Form of Class B Warrant issued to New Investors and DIP Lenders (previously filed on December 5, 2002, as exhibit to Form 10-QSB for quarter ended September 30, 2001, File No. 000-28443, and incorporated by reference herein).
4.4	Form of Series C-1 Warrant to Purchase Shares of Common stock of Cytomedix (previously filed on March 29, 2004 as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein.)
4.5	Form of Series C-2 Warrant to Purchase Shares of Common stock of Cytomedix (previously filed on March 29, 2004 as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).
4.6	Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Stock of Cytomedix as filed with the Delaware Secretary of State on March 25, 2004 (previously filed on March 29, 2004 as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).
4.7	Form of warrant issued to investors in the 2004 Unit Offering (previously filed on May 11, 2004, as exhibit to the registration statement on Form SB-2, File No. 333-115364, and incorporated by reference herein).
4.8	Form of Class D Warrant to Purchase Shares of Common stock of Cytomedix (previously filed on May 2, 2005, as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).

- 4.9 Form of Registration Rights Agreement between Cytomedix, and Class D Warrant holders (previously filed on May 2, 2006, as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 4.10 Form of Warrant (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
- 4.11 Certificate of Designation, Relative Rights and Preferences of the 10% Series D Convertible Preferred Stock (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
- 4.12 Form of Warrant (previously filed on October 8, 2010 as exhibit to the Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 4.13 Form Warrant Agreement (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 4.14 Form Warrant (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 4.15 Certificate of Designation, Relative Rights and Preferences of the Series E Convertible Preferred Stock (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 4.16 Form of Investor Warrant (previously filed on February 20, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 4.17 Warrant (previously filed on February 20, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 4.18 Form 10% Subordinated Convertible Note (previously filed on November 27, 2013 as exhibit to the Current Report on Form 8-K/A and incorporated by reference herein).
- 4.19 Form Common Stock Warrant (previously filed on November 27, 2013 as exhibit to the Current Report on Form 8-K/A and incorporated by reference herein).
- 4.20 Form Convertible Promissory Note (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 4.21 Form Voting Agreement (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 4.22 Form Warrant (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 4.23 Common Stock Purchase Warrant with Anson Investment Master Fund LP, dated March 31, 2014 (previously filed on April 7, 2014, as exhibit to Current Report on Form 8-K and incorporated by reference herein).
- 10.1 Royalty Agreement, dated as of December 26, 2000, by and between Cytomedix and Curative Health Services, Inc. (previously filed on January 17, 2001, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).
- 10.2 First Amendment to Royalty Agreement, dated as of April 20, 2001, by and between Cytomedix and Curative Health Services, Inc. (previously filed on May 25, 2001, as exhibit to the registration statement on Form SB-2/A, File No. 333-55818, and incorporated by reference herein).
- 10.3 Second Amendment to Royalty Agreement, dated as of December 5, 2002, by and between Cytomedix and Curative Health Services, Inc. (previously filed on March 31, 2003, as exhibit to Form 10-KSB for year ended December 31, 2002, File No. 000-28443, and incorporated by reference herein).
- 10.4 Cytomedix Long-Term Incentive Plan.*
- 10.5 License Agreement dated March 21, 2001, by and between Cytomedix and DePuy AcroMed, Inc. (previously filed on April 16, 2001, as exhibit to Form 10-KSB for year ended December 31, 2000, File No. 000-28443, and incorporated by reference herein).
- 10.6 Amendment dated March 3, 2005, to the License Agreement by and between Cytomedix and DePuy Spine, Inc. (f/k/a DePuy Acromed, Inc.) (previously filed on March 31, 2005, as exhibit to Form 10-KSB for year ended December 31, 2004, File No. 000-28443, and incorporated by reference herein).
- 10.7 Second License Agreement dated March 3, 2005, to the License Agreement by and between Cytomedix and DePuy Spine, Inc. (f/k/a DePuy Acromed, Inc.) (previously filed on March 31, 2005, as exhibit to Form 10-KSB for year ended December 31, 2004, File No. 000-28443, and incorporated by reference herein).
- 10.8 Settlement and License Agreement dated May 1, 2005 by and between Cytomedix and Medtronic, Inc. (previously filed on May 10, 2005, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).
- 10.9 Settlement Agreement and License Agreement dated May 23, 2005, by and between Cytomedix, and Harvest Technologies Corporation (previously filed on May 27, 2005, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).

- 10.10 Settlement and License Agreement dated June 26, 2005, by and between Cytomedix, and Perfusion Partners and Associates Inc. (previously filed on August 15, 2005, as exhibit to Form 10-QSB for the quarter ended June 20, 2005, File No. 000-28443, and incorporated by reference herein).
- 10.11 License Agreement dated October 7, 2005, by and between Cytomedix, and COBE Cardiovascular, Inc. (previously filed on October 11, 2005, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).
- 10.12 Settlement and License Agreement dated October 12, 2005, by and between Cytomedix, and SafeBlood Technologies, Inc. (previously filed on November 9, 2005, as exhibit to Form 10-QSB, File No. 000-28443, and incorporated by reference herein).
- 10.13 Employment Agreement with Ms. Carelyn P. Fyllum (previously filed on December 5, 2002, as exhibit to Form 10-QSB for quarter ended September 30, 2001, File No. 000-28443, and incorporated by reference herein).*
- 10.14 Employment Agreement with Kshitij Mohan, Ph.D., dated April 20, 2004 (previously filed on May 7, 2004, on Current Report on Form 8-K, File No. 00028443, and incorporated by reference herein).*
- 10.15 Termination Agreement between Cytomedix, and Kshitij Mohan, dated April 20, 2004 (previously filed on May 7, 2004, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).*
- 10.16 Employment Agreement dated June 3, 2005, by and between Cytomedix, and Andrew Maslan (previously filed on June 20, 2005, as exhibit to Current Report on Form 8-K, File No. 000-28443, and incorporated by reference herein).*
- 10.17 Distributor Agreement dated October 31, 2005 by and between Cytomedix and National Wound Therapies, LLC. (previously filed on March 23, 2006, as exhibit to Form 10-KSB, File No. 001-32518, and incorporated by reference herein).
- 10.18 Settlement and License Agreement dated May 19, 2006, between Cytomedix, and Biomet Biologics, Inc. (previously filed on August 9, 2006, as exhibit to Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.19 First Addendum to Letter Agreement dated October 4, 2006, between Cytomedix, and Andrew Maslan (previously filed on November 1, 2006 as exhibit to Form 10-Q, File No. 001-32518, and incorporated by reference herein).*
- 10.20 License Agreement between Cytomedix, and Smith & Nephew, Inc. (previously filed on October 15, 2007 as exhibit to Current Report on Form 8-K, File No 001-32518, and incorporated by reference herein).
- 10.21 First Amendment to Employment Agreement by and between the Company and Kshitij Mohan (previously filed on January 29, 2008 as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).*
- 10.22 Letter Agreement by and between the Company and Martin Rosendale, dated as of March 14, 2008 (previously filed on March 17, 2008 as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein, and incorporated by reference herein).*
- 10.23 Kshitij Mohan Termination and Consulting Agreement (previously filed on June 10, 2008 as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein, and incorporated by reference herein).*
- 10.24 Form of Securities Purchase Agreement (previously filed on August 26, 2008 as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein, and incorporated by reference herein).
- 10.25 Form Warrant (previously filed on August 12, 2009 as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein, and incorporated by reference herein).
- 10.26 Form Securities Purchase Agreement (previously filed on August 12, 2009 as exhibit to Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 10.27 Form of Transition Agreement, dated as of April 9, 2010 (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
- 10.28 Form of Asset Transfer and Assumption Agreement, dated as of April 9, 2010 (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).

- 10.29 Form of Subscription Agreement (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
- 10.30 Form of Registration Rights Agreement (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
- 10.31 Form of Promissory Note (previously filed on April 12, 2010 as exhibit to the Current Report on Form 8-K, File no. 001-32518, and incorporated by reference herein).
- 10.32 Flex Space Office Lease by and between Cytomedix and Saul Holdings Limited Partnership, dated as of May 19, 2010 (previously filed on August 16, 2010, as exhibit to Form 10-Q for quarter ended June 30, 2010, File No. 001-32518, and incorporated by reference herein).
- 10.33 Form of the Purchase Agreement (previously filed on October 8, 2010 as exhibit to the Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 10.34 Form of the Registration Rights Agreement (previously filed on October 8, 2010 as exhibit to the Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 10.35 Form of the Securities Purchase Agreement (previously filed on October 8, 2010 as exhibit to the Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 10.36 Form of the Lincoln Purchase Agreement (previously filed on October 8, 2010 as exhibit to the Current Report on Form 8-K, File No. 001-32518, and incorporated by reference herein).
- 10.37 Form of Settlement Agreement dated as of April 28, 2011 (previously filed on May 16, 2011 as exhibit to the Company's Quarterly Report on Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.38 Form of Subscription Agreement (previously filed on May 16, 2011 as exhibit to the Company's Quarterly Report on Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.39 Form of Promissory Note dated as of April 28, 2011 (previously filed on May 16, 2011 as exhibit to the Quarterly Report on Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.40 JMJ Promissory Note dated July 15, 2011 (previously filed on August 15, 2011 as exhibit to the Quarterly Report on Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.41 JMJ Letter Agreement and Additional Default Provisions dated July 14, 2011 (previously filed on August 15, 2011 as exhibit to the Quarterly Report on Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.42 JMJ Collateralized Note dated July 15, 2011 (previously filed on August 15, 2011 as exhibit to the Quarterly Report on Form 10-Q, File No. 001-32518, and incorporated by reference herein).
- 10.43 Form Lockup Letter (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.44 Form Voting Agreement (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.45 Form Subscription Agreement (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.46 Lyle A. Hohnke Agreement (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein)*.
- 10.47 Edward Field Employment Letter (previously filed on February 9, 2012 as exhibit to the Current Report on Form 8-K and incorporated by reference herein)*.
- 10.48 Lincoln Park Purchase Agreement (previously filed on February 20, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.49 Lincoln Park Registration Rights Agreement (previously filed on February 20, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.50 Form of Investor Securities Purchase Agreement (previously filed on February 20, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.51 Credit and Security Agreement (previously filed on February 20, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.52 Maslan Separation Agreement dated as of March 30, 2013* (previously filed on May 9, 2013 as exhibit to the Quarterly Report on Form 10-Q and incorporated by reference herein).
- 10.53 Shallcross Employment Letter dated March 30, 2013.* (previously filed on May 9, 2013 as exhibit to the Quarterly Report on Form 10-Q and incorporated by reference herein).
- 10.54 Amendment to the Lincoln Park Capital Purchase Agreement (previously filed on June 11, 2013 as exhibit to the Quarterly Report on Form 10-Q and incorporated by reference herein).

- 10.55 Distributor and License Agreement with Arthrex dated August 7, 2013 (previously filed on November 12, 2013 as exhibit to the Quarterly Report on Form 10-Q and incorporated by reference herein).
- 10.56 Consent and First Amendment to Security Agreement dated August 7, 2013 (previously filed on November 12, 2013 as exhibit to the Quarterly Report on Form 10-Q and incorporated by reference herein).
- 10.57 Form Subscription Agreement (previously filed on November 27, 2013 as exhibit to the Current Report on Form 8-K/A and incorporated by reference herein).
- 10.58 Form Registration Rights Agreement (previously filed on November 27, 2013 as exhibit to the Current Report on Form 8-K/A and incorporated by reference herein).
- 10.59 First Amendment No. 1 to Subscription Agreement dated December 3, 2013 (previously filed on December 3, 2013 as exhibit to the Current Report on Form 8-K and incorporated by reference herein).
- 10.60 Facility Agreement, dated March 31, 2014 (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 10.61 Guaranty and Security Agreement with Deerfield, among others, dated March 31, 2014 (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 10.62 Registration Rights Agreement dated March 31, 2014 (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 10.63 Subscription Agreement with Anson Investment Master Fund LP dated March 31, 2014 (previously filed on April 7, 2014, as exhibit to Current Report on Form 8-K and incorporated by reference herein).
- 10.64 Registration Rights Agreement dated March 31, 2014 (previously filed on April 7, 2014, as exhibit to Current Report on Form 8-K and incorporated by reference herein).
- 10.65 Martin P. Rosendale Employment Agreement dated May 14, 2014 (previously filed on May 15, 2014, as exhibit to Annual Report on Form 10-Q and incorporated by reference herein).*
- 10.66 Employment Agreement for S. Shallcross dated as of May 30, 2014 (previously filed on May 30, 2014, as exhibit to Current Report on Form 8-K and incorporated by reference herein).*
- 10.67 Employment Agreement for D. Tozer dated as of May 30, 2014 (previously filed on May 30, 2014, as exhibit to Current Report on Form 8-K and incorporated by reference herein).*
- 10.68 Employment Agreement for P. Clausen dated as of as of May 30, 2014 (previously filed on May 30, 2014, as exhibit to Current Report on Form 8-K and incorporated by reference herein).*
- 10.69 First Amendment to the Deerfield Facility Agreement and Registration Rights Agreement dated as of June 25, 2014 (previously filed on July 1, 2014 as an exhibit to our Current Report on Form 8-K, and incorporated herein by reference)
- 10.70 Amendment to Employment Agreement for M. Rosendale (previously filed on July 18, 2014, as exhibit to Current Report on Form 8-K/A and incorporated by reference herein).*
- 10.71 Amendment to Employment Agreement for S. Shallcross (previously filed on July 18, 2014, as exhibit to Current Report on Form 8-K/A and incorporated by reference herein).*
- 10.72 Amendment to Employment Agreement for D. Tozer (previously filed on July 18, 2014, as exhibit to Current Report on Form 8-K/A and incorporated by reference herein).*
- 10.73 Amendment to Employment Agreement for P. Clausen (previously filed on July 18, 2014, as exhibit to Current Report on Form 8-K/A and incorporated by reference herein).*
- 10.74 Form Indemnification Agreement. (previously filed on November 13, 2014, as exhibit to our Quarterly Report on Form 10-Q, and incorporated by reference herein).
- 10.75 Second Amendment to the Exchange and Purchase Agreement, dated November 11, 2014, by and among, Cytomedix, Inc., Aldagen, Inc., and Aldagen Holdings, LLC, (previously filed on November 13, 2014, as exhibit to our Quarterly Report on Form 10-Q, and incorporated by reference herein).
- 21.1 Subsidiaries of the Company (previously filed on March 31, 2014, as exhibit to Annual Report on Form 10-K and incorporated by reference herein).
- 23.1 Consent of Stegman & Company (Filed herewith).
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (Filed herewith)
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (Filed herewith)
- 32.1 Certificate of Chief Executive Officer pursuant to 18 U.S.C.ss.1350. (Furnished herewith)
- 32.2 Certificate of Chief Financial Officer pursuant to 18 U.S.C.ss.1350. (Furnished herewith)
- (101) The following financial statements from the Nuo Therapeutics, Inc. Annual Report on Form 10-K for the year ended December 31, 2014, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2014 and December 31, 2013, (ii) Consolidated Statements of Operations for the years ended December 31, 2014 and 2013, (iii) Consolidated Statements of Redeemable Common Stock and Stockholders' Equity for the years ended December 31, 2014 and 2013, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013, and (v) Notes to Consolidated Financial Statements (Filed herewith).

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Indicates a management contract or compensatory plan or arrangement.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (Nos. 333-168936, 333-183704, and 333-183703) and the Registration Statement on Forms S-8 (Nos. 333-197262, 333-191632, 333-120141, and 333-162135) of Nuo Therapeutics, Inc. of our report dated March 31, 2015 relating to the consolidated balance sheets of Nuo Therapeutics, Inc. as of December 31, 2014 and 2013, and the related consolidated statements of operations, redeemable common stock and stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2014 which appears in this Annual Report on Form 10-K.

/s/ Stegman & Company

Baltimore, Maryland
March 31, 2015

CERTIFICATION

I, Martin P. Rosendale, certify that:

1. I have reviewed this Form 10-K of Nuo Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 31, 2015

/s/ Martin P. Rosendale
Martin P. Rosendale,
Chief Executive Officer

A signed original of this written statement has been provided to Nuo Therapeutics, Inc. and will be retained by Nuo Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION

I, Steven A. Shallcross, certify that:

1. I have reviewed this Form 10-K of Nuo Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 31, 2015

/s/ Steven A. Shallcross
Steven A. Shallcross,
Chief Financial Officer

A signed original of this written statement has been provided to Nuo Therapeutics, Inc. and will be retained by Nuo Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. §1350**

Pursuant to 18 U.S.C. §1350 and in connection with the Annual Report on Form 10-K of Nuo Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2014 (the "Report"), I, Martin P. Rosendale, Chief Executive Officer of the Company, hereby certify that to the best of my knowledge and belief:

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

Date: March 31, 2015

/s/ Martin P. Rosendale
Martin P. Rosendale
Chief Executive Officer

A signed original of this written statement has been provided to Nuo Therapeutics, Inc. and will be retained by Nuo Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. §1350**

Pursuant to 18 U.S.C. §1350 and in connection with the Annual Report on Form 10-K of Nuo Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2014 (the "Report"), I, Steven A. Shallcross, Chief Financial Officer of the Company, hereby certify that to the best of my knowledge and belief:

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

Date: March 31, 2015

/s/ Steven A. Shallcross
Steven A. Shallcross
Chief Financial Officer

A signed original of this written statement has been provided to Nuo Therapeutics, Inc. and will be retained by Nuo Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
