Arno Therapeutics, Inc
Form 424B3
April 19, 2016

**Filed Pursuant to Rule 424(b)(3)**

**File No. 333-210102**

**OFFERING PROSPECTUS**

**21,153,997 Shares**

**Common Stock**

The selling stockholders identified beginning on page 19 of this prospectus are offering on a resale basis a total of 21,153,997 shares of our common stock. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is quoted on the OTCQB tier of the OTC Markets under the symbol “ARNI.” On April 18, 2016, the last sale price of our common stock as reported on the OTCQB was $0.37.

**The securities offered by this prospectus involve a high degree of risk.**

**See “Risk Factors” beginning on page 6.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined that this prospectus is truthful or complete. A representation to the contrary is a criminal offense.**

**The date of this prospectus is April 18, 2016.**

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**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including the risks of investing in our securities discussed under the caption "Risk Factors" and the financial statements and other information that is contained in or incorporated by reference into this prospectus or the registration statement of which this prospectus is a part before making an investment decision. Unless the context otherwise requires, hereafter in this prospectus the terms the "Company," "Arno," "we," "us," or "our" refer to Arno Therapeutics, Inc., a Delaware corporation.*

**Company Overview**

We are focused on developing innovative products for the treatment of cancer and other life threatening diseases. We currently have exclusive worldwide rights to three innovative clinical stage compounds with unique mechanisms of action that have the potential to be first-in-class therapeutics. The following is a summary of our product development pipeline:

- ***Onapristone –*** We are currently developing onapristone, an oral anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in patients with breast cancer. Onapristone appears to have a unique ability to block the activation of the progesterone receptor and inhibit tumor growth. In connection with the development of onapristone, we have engaged Leica Biosystems to develop an immunohistochemistry based diagnostic test to identify tumors with the activated form of the progesterone receptor (APR), which is intended to identify patients more likely to benefit from treatment with onapristone. Additional biomarker development is ongoing to develop a diagnostic test to identify progesterone receptor (PR) in tumor types other than breast cancer.

In April 2014, we enrolled the first patient in a Phase I/II clinical trial of onapristone in men with advanced castration-resistant prostate cancer, or CRPC, after failure of abiraterone or enzalutamide. This study is currently being conducted at three sites in the United Kingdom, led by the Royal Marsden NHS Foundation Trust in London. The randomized, open-label trial is designed to evaluate the safety and anti-cancer activity of onapristone in the defined patient population. The Phase I component of the study evaluated onapristone extended-release tablet formulations in five dose levels (10-50 mg, twice daily) in patients with prostate cancer and has completed enrollment. The protocol has been amended to study the combination of onapristone plus abiraterone in a Phase I setting with an expansion phase. In addition, the protocol also includes a Phase II cohort of patients that will be enrolled to gain additional understanding of the onapristone as a potential treatment in men with CRPC. The Phase II aspect of the study includes; a component that will evaluate the combination of onapristone plus abiraterone acetate in men who have had evidence of progression of disease while on abiraterone acetate. Another component of this Phase II aspect of the study will further evaluate the safety profile and potential anti-cancer activity of single agent onapristone in men with advanced CRPC after failure of abiraterone or enzalutamide. In accordance with the modified Phase II study

protocol, study subjects will be evaluated for whether their tumors express PR/APR or the T878A androgen receptor mutation, which may help identify patients who are more likely to respond to onapristone in future studies. Screening of patients under the amended study protocol began in the first quarter of 2016 and the Phase II study will include approximately 75 patients.

In addition, in December 2014, we enrolled the first patient in the expansion phase of our ongoing Phase I/II clinical trial evaluating onapristone in women with progesterone receptor (PR) expressing tumors. The protocol was subsequently amended to include a formal Phase II study in patients with recurrent or metastatic endometrioid tumors that have been shown to express PR, and who have received no more than one prior chemotherapy and no prior hormone therapy. Patients in the Phase II component of the study received 50mg of extended release onapristone twice daily, the dose determined by an independent data review committee to be safely administered to patients based on the results of the Phase I component of this study. The study also incorporated a diagnostic test targeting women with tumors expressing APR, which was intended to select those patients more likely to respond to onapristone treatment. In April 2016, we determined to close this clinical trial in order to focus our resources on our prostate cancer program.

***AR-12 and analogues –*** AR-12 was initially being developed as an orally available agent which demonstrated to inhibit multiple different kinase targets. We believe AR-12 may also cause malignant cell death through the induction of stress in the endoplasmic reticulum and recent work has demonstrated that AR-12 inhibits various molecular protein chaperones including GRP78, HSP70, HSP90 and HSP27. We have completed a Phase I clinical trial of AR-12 in adult patients with advanced or recurrent solid tumors or lymphoma using the original non optimized formulation of AR-12. Subsequently, an improved formulation of AR-12 that has been shown to substantially increase bioavailability in preclinical models has been developed. Based on additional pre-clinical research conducted on AR-12, we are currently pursuing various opportunities with the potential for securing non-dilutive funding, via government and philanthropic agency grants and contracts, for further research into the potential use of AR-12 as an anti-microbial agent. In April 2015, the EMA granted two orphan drug designations for AR-12 for the treatment of cryptococcosis and tularaemia. Cryptococcosis is an infectious disease of the lungs caused by the fungus *Cryptococcus neoformans* and is one of the most common life-threatening fungal infections in people with AIDS. Tularaemia is an infection which can be spread from animals to humans that is caused by the bacterium *Francisella tularensis* and is a Category A Priority Pathogen on the National Institute of Allergy and Infectious Disease (NIAID) list of Biodefense and Emerging Infectious Diseases. A CRADA is in place with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) for the evaluation of AR-12 and four analogues against pathogens of biodefense interests. Other analogues of AR-12 such as AR-13 are being investigated for activity against certain microbial pathogens through a number of collaborations.

- ***AR-42 –*** AR-42 is being developed as an orally available, broad spectrum inhibitor of both histone and non-histone deacetylation proteins, or Pan-DAC, which play an important role in the regulation of gene expression, cell growth and survival. AR-42 recently completed an investigator-initiated dose escalation clinical study with an expansion phase in adult subjects with relapsed or refractory hematological malignancies (multiple myeloma, chronic lymphocytic leukemia (CLL), or lymphoma) and solid tumors. The recommended Phase II dose, or RP2D, in patients with hematological malignancies has been determined and the expansion phase of the program has been completed. The protocol has been amended to include a separate solid tumor dose escalation cohort and expansion phase. The solid tumor component of the study has been completed. We also supported an investigator initiated Phase I study of AR-42 in combination with decitabine in patients with hematological malignancies that was initiated during the third quarter of 2013. The FDA has granted two orphan drug designations for AR-42 for the treatment of meningioma and the treatment of schwannoma of the central nervous system. Meningioma and schwannoma are rare, benign tumors that can present in different locations within the brain and the spinal cord and may cause substantial morbidity for those affected individuals. Additionally, AR-42 has been granted three orphan drug designations by the European Medicines Agency, or EMA, for the treatment of neurofibromatosis type 2 (NF2), the treatment of meningioma and the treatment of schwannoma. NF2 is a rare genetic disorder characterized by the growth of noncancerous tumors in the brain and spinal cord, juvenile cataracts, and neurofibromas of the skin. Additional investigator sponsored clinical trials of AR-42 are currently underway or being planned.

In June 2008, we were acquired by Laurier International, Inc., a Delaware corporation, in a “reverse” merger whereby a wholly-owned subsidiary of Laurier merged with and into Arno Therapeutics, with Arno Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of Laurier. In accordance with the terms of this merger, stockholders of Arno Therapeutics exchanged all of their shares of common stock of Arno Therapeutics for shares of Laurier common stock at a rate of 1.99377 shares of Laurier common stock for each share of Arno Therapeutics common stock. As a result of the issuance of the shares of Laurier common stock to the former Arno Therapeutics stockholders, following the merger the former stockholders of Arno Therapeutics held 95 percent of the outstanding common stock of Laurier, assuming the issuance of all shares underlying outstanding options and warrants. Upon completion of the merger, all of the former officers and directors of Laurier resigned and were replaced by the officers and directors of Arno Therapeutics. Additionally, following the merger Laurier changed its name to Arno Therapeutics, Inc.

Our executive offices are located at 200 Route 31 North, Suite 104, Flemington, New Jersey 08822. Our telephone number is (862) 703-7170. Our website is *www.arnothera.com*. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

**Risk Factors**

As with most biopharmaceutical product candidates, the development of our product candidates is subject to numerous risks, including the risk of delays in or discontinuation of development from lack of financing, inability to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we have only

development-stage product candidates and a limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled “Risk Factors” beginning on page 6 of this prospectus.

**The Offering**

The selling stockholders identified beginning on page 19 of this prospectus are offering on a resale basis a total of 21,153,997 shares of our common stock. The total value of all the common stock offered pursuant to this prospectus is approximately $7.8 million, based upon a per share price of $0.37, which represents the average of the high and low prices of our common stock as reported on the OTCQB on April 18, 2016.

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|---|---|
| Common stock offered | 21,153,997 shares |
| Common stock outstanding before the offering [(1)] | 41,562,613 shares |
| Common stock outstanding after the offering | 41,562,613 shares |
| Use of Proceeds | We will receive none of the proceeds from the sale of the shares by the selling stockholders. |
| OTCQB Symbol | ARNI |

(1) Based on the number of shares outstanding as of April 18, 2016, not including 58,076,107 shares issuable upon exercise of various warrants and options to purchase our common stock.

**Recent Developments**

***2016 Offering***

On January 12, 2016, we entered into a Stock Purchase Agreement with certain purchasers identified therein pursuant to which we sold and the purchasers purchased an aggregate of 21,153,997 shares of common stock at a purchase price of $0.35 per share, resulting in aggregate gross proceeds to us of approximately $7.4 million, including approximately $2.1 million from the automatic conversion of outstanding promissory notes. These transactions, which were completed on January 12, 2016, are referred to as the 2016 Offering. The terms and conditions of the 2016 Offering are more fully described in this prospectus under the caption “Description of 2016 Offering.”

***Onapristone Development Program***

In April 2016, we made a strategic decision to focus our resources on our Onapristone prostate cancer program and to therefore begin closing our ongoing Phase II clinical trial of Onapristone in patients with recurrent or metastiatic endometrioid tumors. This decision was not based on any safety or lack of efficacy signal and we will continue to provide Onapristone to all patients currently enrolled in this trial on a compassionate use basis.

**RISK FACTORS**

*Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this prospectus, before making an investment decision regarding our common stock. If any of these risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.*

**Risks Relating to Our Business**

***We currently have no product revenues and need substantial additional funding in order to continue our business operations and the further development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development programs and may be forced to cease our operations altogether.***

We are in immediate need of additional capital to fund our operations. As of December 31, 2015, we had approximately $0.1 million in cash and cash resources, and negative net working capital of approximately $3.9 million. During the year ended December 31, 2015, we had negative cash flow from operating activities of $10.0 million, and we expect our negative cash flows from operations to continue for the foreseeable future. Including the proceeds received from our recent financing transactions, we believe that we have sufficient capital to fund our operations through approximately May 2016 based on the current plan of expenditure on continuing development of the current product candidates. Further, beyond funding our basic corporate activities, we require substantial additional funds to support our continued research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization.

Since we do not currently generate any revenue from operations, nor do we expect to for the foreseeable future, the most likely sources of such additional capital include private placements of our equity securities, including our common stock or securities convertible into or exchangeable for our common stock, debt financing or funds from a potential strategic licensing or collaboration transaction in which we would license or otherwise relinquish the rights to one or more of our product candidates. To the extent that we raise additional capital by issuing equity securities, our stockholders will likely experience dilution, which may be significant depending on the number of shares we may issue and the price per share. If we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies, product candidates or products, or grant licenses on terms that are not favorable to us. If we raise additional funds by incurring debt, we could incur significant interest expense and become subject to restrictive covenants that could affect the manner in which we conduct our business.

We currently have no committed sources of additional capital and our access to capital funding is always uncertain. Despite our ability to secure adequate capital in the past, there is no assurance that additional equity or debt financing will be available to us when needed, on acceptable terms or even at all. If we fail to obtain the necessary additional capital when needed, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs. In addition, we could be forced to discontinue product development, reduce or forego attractive business opportunities and even cease our operations altogether.

***As an early-stage enterprise engaged in the development of new biotechnology and biopharmaceutical compounds, we are subject to numerous risks relating to the development of our product candidates.***

We have not received any operating revenues to date and you should be aware of the problems, delays, expenses and difficulties encountered by an enterprise engaged in the development of new biotechnology or biopharmaceutical product candidates, many of which may be beyond our control. These include, but are not limited to, problems relating to product development, testing, regulatory compliance, manufacturing, marketing, costs and expenses that may exceed current estimates and competition. No assurance can be given that our existing product candidates, or any technologies or products that we may acquire in the future will be successfully developed, commercialized and accepted by the marketplace or that sufficient funds will be available to support operations or future research and development programs.

***We do not generate revenue or positive cash flows from operations and may never do so.***

We do not generate revenue and expect to incur negative operating cash flows for the foreseeable future, and we may never achieve or maintain positive operating cash flow. For the years ended December 31, 2015 and 2014, we had negative cash flows from operating activities of $10.0 million and $18.8 million, respectively. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur negative operating cash flows for the foreseeable future, as we:

- continue to undertake pre-clinical development and clinical trials for our product candidates;

- seek regulatory approvals for our product candidates;

- in-license or otherwise acquire additional products or product candidates;

- seek patent protection for our product candidates;

- implement additional internal systems and infrastructure; and

- hire additional personnel.

As a result, we will need to generate significant revenues in order to achieve and maintain positive operating cash flows. We may not be able to generate these revenues and this could negatively impact the value of our common stock.

***We have a limited operating history upon which to base an investment decision.***

We have not received regulatory approval for any of our product candidates and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials for our product candidates;

- participating in regulatory approval processes;

- formulating and manufacturing products; and

- conducting sales and marketing activities.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technologies and performing pre-clinical and clinical trials of our product candidates. These operations provide a

limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

***We may not successfully manage our growth.***

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

***Certain of our directors are officers and directors of other biotechnology companies, which may present potential conflicts of interest.***

Some of our directors serve as officers and directors of other biotechnology and life science companies, some of which may be considered a potential competitor of ours. See "Management and Board of Directors – Directors and Executive Officers." We do not believe that any of the other companies on whose board of directors members of our board sit compete directly with us and our product candidates. However, there can be no assurance that such other companies will not in the future have interests in conflict with our own.

***We are substantially dependent on the services of various consultants.***

We currently have four employees and we rely in substantial part, and for the foreseeable future will continue to rely, on certain independent organizations and consultants to provide other important services, including substantially all aspects of regulatory approval, clinical management, and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements.

***If we are unable to hire additional qualified personnel in the future, our ability to grow our business may be harmed.***

We have only four full-time employees and continue to rely on various third parties to perform a variety of management, clinical operations and other services on our behalf on a consulting basis. As we continue with the development of our product candidates, we expect that we will need to hire additional employees, including a chief financial officer and other senior management positions. Accordingly, our ability to attract and retain qualified

personnel will be critical to managing and growing our business in the future, especially the hiring and retention of key executive personnel and scientific staff. There is intense competition and demand for qualified personnel in our area of business and no assurances can be made that we will be able to retain the personnel necessary for the development of our business on commercially reasonable terms, if at all.

***We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.***

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products candidates, if approved. Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- withdrawal of prior governmental approvals;
- costs of related litigation;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

Because we do not yet have any products approved for sale, we currently do not carry product liability insurance. While we intend to obtain product liability insurance prior to any commercial product sales, such insurance coverage may not be adequate to cover claims against us or available to us at an acceptable cost, if at all. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of the pharmaceutical products we develop, alone or with commercialization partners. Even if our agreements with any future commercialization partners entitle us to indemnification against damages from product liability claims, such indemnification may not be available or adequate should any claim arise.

***We may incur substantial liabilities in connection with the clinical trials of our product candidates and may be required to cease our clinical trials in response to lawsuits brought by clinical trial participants.***

Conducting clinical trials entails an inherent risk of liability resulting from lawsuits brought by clinical trial participants who experience unexpected adverse reactions to our product candidates or as a result of the medical care they receive while participating in a clinical trial. If we cannot successfully defend ourselves against such claims, we may incur substantial liabilities or be required to cease clinical trials of our products candidates, which would have a material adverse effect on our business, financial condition and results of operations. We currently maintain a clinical trial insurance policy with a $5 million per occurrence and aggregate limit, which may not be adequate to cover claims against us. While our agreements with the research institutions that conduct our clinical trials often provide that the institutions will indemnify us against damages from claims brought by clinical trial participants that result from the institutions' conduct, such indemnification may not be available or adequate should any such claim arise.

***We are controlled by current directors and principal stockholders.***

Our executive officers, directors and principal stockholders (i.e. those beneficially owning more than 5% of our outstanding voting securities) beneficially own a large majority of our outstanding voting securities. Accordingly, our executive officers, directors, principal stockholders and certain of their affiliates will have the ability to exert substantial influence over the election of our board of directors and the outcome of issues submitted to our stockholders.

***The co-lead investors in our September 2010 private placement own a significant amount of our voting securities and are entitled to substantial governance rights that may limit our management's autonomy.***

Our September 2010 private placement was co-led by three investors – Pontifax (investing through three affiliated funds: Pontifax (Cayman) II L.P., Pontifax (Israel) II Individual Investors L.P., and Pontifax (Israel) II L.P., which we collectively refer to as "Pontifax"), Commercial Street Capital, LLC ("Commercial Street Capital"), and UTA Capital LLC ("UTA Capital"). Pursuant to the terms of the purchase agreement that we entered into with the investors in our 2010 private placement, each co-lead investor has the right to designate one individual to be appointed to our board of directors, subject to certain ownership and other requirements and conditions. Moreover, the 2010 purchase agreement provides that each such director has the right to serve on any or all of the committees of our board of directors. The purchase agreement also provides that the affirmative vote of each such investor-designated director then in office shall be required to approve the appointment of our chief executive officer and to authorize certain transactions between us and one of our officers, directors, principal stockholders or their affiliates. Pursuant to their rights under the purchase agreement, Pontifax, Commercial Street Capital, and UTA Capital designated Tomer Kariv, Steven Ruchefsky, and Yacov Reizman, respectively, for appointment to our board of directors. This concentration of ownership and governance rights among the co-lead investors may not be in the best interests of all our stockholders. The co-lead investors will be able to exert significant control over our management and affairs requiring stockholder approval, including approval of significant corporate transactions. Such concentration of voting power could have the effect of delaying or preventing a change of control or other business combination, and may adversely affect the market price of our common stock.

***We are required to maintain finance and accounting systems, procedures and controls in order to satisfy requirements under the securities laws, including the Sarbanes-Oxley Act of 2002, which increase our costs and divert management's time and attention.***

We have established processes, controls and procedures that allow our management to report on our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. As a company with limited capital and human resources, the diversion of management's time and attention away from our business to ensure compliance with these regulatory requirements may have a material adverse effect on our business, financial condition and results of operations.

In the event we identify significant deficiencies or material weaknesses in our internal controls over financial reporting that we cannot remediate in a timely manner, investors and others may lose confidence in the reliability of our financial statements. If this occurs, the trading price of our common stock, if any, and our ability to obtain any necessary financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal controls over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our periodic reports with the SEC. This would likely have an adverse effect on the trading price of our common stock, if any, and our ability to

secure any necessary additional financing, and could result in the delisting of our common stock if we are listed on an exchange in the future. In such event, the liquidity of our common stock would be severely limited and the market price of our common stock would likely decline significantly.

**Risks Relating to the Clinical Testing, Regulatory Approval, Manufacturing**

**and Commercialization of Our Product Candidates**

***We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidates.***

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a new drug application, or NDA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; or
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure that we will receive the approvals necessary to commercialize our product candidate for sale outside the U.S.

***All of our product candidates are in the very early stages of development and will require extensive clinical trials before they may be approved for marketing. Clinical trials are very expensive and time-consuming. Any failure or delay in completing clinical trials for our product candidates could harm our business.***

All of our current product candidates are in early stages of development and will require extensive clinical and other testing and analysis before we will be in a position to consider seeking regulatory approval to sell such product candidates. Conducting clinical trials is a lengthy, time consuming and very expensive process and the results are inherently uncertain. The duration of clinical trials can vary substantially according to the type, complexity, novelty and intended use of the product candidate. We estimate that clinical trials of our product candidates will take at least several years to complete. The completion of clinical trials for our product candidates may be delayed or prevented by many factors, including without limitation:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, side effects, or other adverse events;
- results that do not demonstrate the safety or effectiveness of the product candidates;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and

· varying interpretation of data by the FDA.

In conducting clinical trials, we may fail to establish the effectiveness of a compound for the targeted indication or discover that it is unsafe due to unacceptable side effects or other reasons. Even if our clinical trials are commenced and completed as planned, their results may not support our product candidate claims. Further, failure of product candidate development can occur at any stage of clinical trials, or even thereafter, and we could encounter problems that cause us to abandon or repeat clinical trials. These problems could interrupt, delay or halt clinical trials for our product candidates and could result in FDA, or other regulatory authorities, delaying or declining approval of our product candidates for any or all indications. The results from pre-clinical testing and prior clinical trials may not be predictive of results obtained in later or other larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. Our failure to adequately demonstrate the safety and effectiveness of any of our product candidates will prevent us from receiving regulatory approval to market these product candidates and will negatively impact our business. In addition, we or the FDA may suspend or curtail our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in the conduct of these clinical trials or in the composition, manufacture or administration of the product candidates. Accordingly, we cannot predict with any certainty when or if we will ever be in a position to submit a new drug application, or NDA, for any of our product candidates, or whether any such NDA would ever be approved.

***Our products use novel alternative technologies and therapeutic approaches, which have not been widely studied.***

Our product development efforts focus on novel therapeutic approaches and technologies that have not been widely studied. These approaches and technologies may not be successful. We are applying these approaches and technologies in our attempt to discover new treatments for conditions that are also the subject of research and development efforts of many other companies.

***Physicians and patients may not accept and use our drugs.***

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our products will depend upon a number of factors including:

· perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;

- cost-effectiveness of our products relative to competing products;

- availability of reimbursement for our products from government or other healthcare payers; and

- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

***Because we are dependent on clinical research organizations and other contractors for clinical testing and for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, not within our control.***

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

***Our reliance on third parties to formulate and manufacture our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.***

We have no direct experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. Instead, we will contract with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. If any of our product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and/or commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we will be ultimately responsible for any of their failures.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. This may prohibit us from seeking alternative or additional manufacturers for our products.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

***We have no direct experience selling, marketing or distributing products and no internal capability to do so.***

We currently have no sales, marketing or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the U.S. or overseas.

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***If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.***

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have technologies already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

***Developments by competitors may render our products or technologies obsolete or non-competitive*** .

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the U.S. and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development

staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

***Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.***

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

***We may be exposed to liability claims associated with the use of hazardous materials and chemicals.***

Our research and development activities may involve the controlled use of hazardous materials and chemicals by our third-party service providers. Although we believe that our service providers maintain appropriate safety procedures for using, storing, handling and disposing of these materials in compliance with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us or our service providers to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations. We do not carry insurance against liability resulting from the use of hazardous materials and chemicals. While we generally require our service providers to carry insurance against liability resulting from their use of such materials, we cannot be certain that such insurance will be sufficient to cover any related liability. To the extent our service providers fail to carry adequate levels of insurance, we could be exposed to liability claims associated with their use of hazardous materials and chemicals.

**Risks Related to Our Intellectual Property**

***If we fail to protect or enforce our intellectual property rights adequately or secure rights to patents of others, the value of our intellectual property rights would diminish.***

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing upon the proprietary rights of third parties. Additionally, if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

To date, we hold certain exclusive rights under U.S. patents and patent applications as well as rights under foreign patent applications. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- if and when patents will issue;

- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or

- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

***If any of our know-how or other proprietary information is disclosed, the value of our know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.***

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our know-how or other proprietary information is disclosed, the value of our know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

***If we infringe upon the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.***

If our products, methods, processes and other technologies infringe upon the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

***If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our products.***

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. We have licensed rights from Invivis Pharmaceuticals, Inc. and The Ohio State University Research Foundation. These agreements require us and our licensors to perform certain obligations that affect our rights under these licensing agreements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

**Risks Related to Our Securities**

***The exercise of our outstanding warrants could cause the market price of our common stock to fall, and may have significant dilution and other effects on our existing stockholders.***

In each of 2012 and 2013, we issued warrants, which we refer to as the 2012 Warrants and the 2013 Warrants, respectively, to certain holders to purchase an aggregate of approximately 42.6 million shares of our common stock. The exercise prices applicable to the 2012 Warrants and to some of the 2013 Warrants are subject to adjustment pursuant to certain anti-dilution provisions. The issuance by us of the shares of common stock issuable upon exercise of the 2012 and 2013 Warrants would significantly reduce the percentage ownership of our existing common stockholders and could, among other things, depress the price of the common stock. This result could significantly and adversely affect our ability to raise additional equity capital in the future.

As if December 31, 2015, following the January 31, 2015 expiration of certain 2012 Warrants and 2013 Warrants, and immediately prior to the 2016 Offering, the remaining unexpired 2012 Warrants and 2013 Warrants consisted of the following:

- Warrants to purchase an aggregate of 10,317,464 shares at an exercise price of 2.40 per share (the “2012 Series A Warrants”);
- Warrants to purchase an aggregate of 4,455,231 shares at an exercise price of $0.01 per share (the “2013 Series C Warrants”); and
- Warrants to purchase an aggregate of 12,868,585 shares at an exercise price of $4.00 per share (the “2013 Series D Warrants”).

The exercise prices of the 2012 Series A Warrants and 2013 Series D Warrants (but not the 2013 Series C Warrants) are subject to a weighted-average price adjustment in the event we sell or issue additional shares of our common stock (subject to certain exceptions) at a price per share less than the applicable exercise prices. The 2016 Offering, which involved the sale of our common stock at a price per share of $0.35, therefore triggered the anti-dilution provisions of the 2012 Series A Warrants and 2013 Series D Warrants and resulted in their exercise prices being reduced from $2.40 and $4.00 to $1.36 and $2.14, respectively. In accordance with provisions of the 2012 Series A Warrants and 2013 Series D Warrants requiring that the warrants’ aggregate exercise prices remain the same following any reduction in exercise price, the aggregate number of shares issuable upon exercise of the 2012 Series A Warrants was increased from 10,317,464 to 18,207,273 and the aggregate number of shares issuable upon exercise of the 2013 Series D Warrants was increased from 12,868,585 to 24,053,398. Following these adjustments, if we make future issuances of common stock or rights to acquire common stock (subject to certain exceptions) at a per share price less than the applicable exercise prices of the 2012 Series A Warrants and 2013 Series D Warrants, then the applicable exercise prices (and share amounts) remain subject to further adjustment.

We expect that we will need substantial additional capital in order to fund our operations during the applicable terms of the 2012 Warrants and the 2013 Warrants and that a likely source of such capital will be through the sale and issuance of additional shares of our common stock or securities convertible into our common stock. Consequently, if we make such future issuances at prices lower than the applicable 2012 Series A Warrant or 2013 Series D Warrant exercise prices, our stockholders could experience significant additional dilution of their investment.

The holders of the 2012 Warrants and the 2013 Warrants may immediately sell the full amount of common stock received upon conversion or exercise of such instruments. As these shares are sold, the price of the common stock is likely to decrease, perhaps substantially, unless there is sufficient demand by purchasers of our common stock in the trading markets to meet the additional volume of shares of our common stock available from the exercise of the 2012 Warrants and the 2013 Warrants.

***We cannot assure you that our common stock will ever be listed on NASDAQ or any other securities exchange.***

Our common stock is currently eligible for trading on the OTCQB tier of the OTC Markets, an automated quotation system. Stocks traded on the OTCQB and other electronic over-the-counter markets are often less liquid than stocks traded on national securities exchanges. In fact, the historical trading of our common stock has been extremely limited and sporadic. We may seek listing on NASDAQ or another national securities exchange in the future, but we cannot assure you that we will be able to meet the initial listing standards of any stock exchange, or that we will be able to maintain a listing of our common stock on either of those or any other stock exchange. To the extent that our common stock is not traded on a national securities exchange, such as NASDAQ, the decreased liquidity of our common stock may make it more difficult to sell shares of our common stock at desirable times and at prices.

***Our common stock is considered a "penny stock."***

The SEC has adopted regulations which generally define a "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. Since trading of our common stock commenced, the market price has been below $5.00 per share. Therefore, our common stock is deemed a "penny stock" according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell shares of our common stock.

***Because we did not become public through an underwritten initial public offering, we may not be able to attract the attention of major brokerage firms.***

Additional risks may exist since we did not become public through an initial public offering underwritten by an investment bank. Security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of our company in the future. The lack of such analyst coverage may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate

***Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.***

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our common stock if you require dividend income. Further, you will only realize income on an investment in our shares in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

***There may be issuances of shares of "blank check" preferred stock in the future.***

Our amended and restated certificate of incorporation authorizes the issuance of up to 35,000,000 shares of preferred stock, none of which are issued or currently outstanding. Our board of directors has the authority to fix and determine the relative rights and preferences of up to 35,000,000 preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that is senior to our common stock and that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption to such shares, together with other rights, none of which will be afforded holders of our common stock.

***If we obtain an analyst following, and if our results do not meet such analysts' forecasts and expectations, our stock price could decline.***

We do not believe that any securities analysts cover us. The lack of analyst coverage of our business and operations may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate. To the extent we obtain an analyst following in the future, such analysts may provide valuations regarding our stock price and make recommendations whether to buy, hold or sell our stock. Our stock price may be dependent upon such valuations and recommendations. Analysts' valuations and recommendations are based primarily on our reported results and their forecasts and expectations concerning our future results regarding, for example, expenses, revenues, clinical trials, regulatory marketing approvals and competition. Our future results are subject to substantial uncertainty, and we may fail to meet or exceed analysts' forecasts and expectations as a result of a number of factors, including those discussed above under the sections "Risks Related to Our Business" and "Risks Related to the Clinical Testing, Regulatory Approval, Manufacturing and Commercialization of Our Product Candidates." If our results do not meet analysts' forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise.

***We are at risk of securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

**NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains "forward-looking statements." The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "
"will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, our research and development programs and planning for and timing of any clinical trials, the possibility, timing and outcome of submitting regulatory filings for our product candidates under development, research and development of particular drug products, the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations.

Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Examples of the risks and uncertainties include, but are not limited to:

- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- the risk that we may not successfully develop and market our product candidates, and even if we do, we may not become profitable;
- risks relating to the progress of our research and development;
- risks relating to significant, time-consuming and costly research and development efforts, including pre-clinical studies, clinical trials and testing, and the risk that clinical trials of our product candidates may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for any products that we may develop independently, with our development partners or in connection with any collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;

- risks that the FDA or other regulatory authorities may not accept any applications we file;

- risks that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we file or limit such applications to particular indications or apply other label limitations;

- risks that, after acceptance and review of applications that we file, the FDA or other regulatory authorities will not approve the marketing and sale of our drug product candidates;

- risks relating to our drug manufacturing operations, including those of our third-party suppliers and contract manufacturers;

- risks relating to the ability of our development partners and third-party suppliers of materials, drug substance and related components to provide us with adequate supplies and expertise to support manufacture of drug product for initiation and completion of our clinical studies;

- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers; and

- other risks and uncertainties detailed in “Risk Factors.”

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

**DESCRIPTION OF 2016 OFFERING**

**General**

On January 12, 2016, we entered into a Stock Purchase Agreement with certain purchasers identified therein pursuant to which we agreed to sell, and the purchasers agreed to purchase, an aggregate of 21,153,997 shares of common stock at a purchase price of $0.35 per share, resulting in aggregate gross proceeds of approximately $7.4 million, including approximately $2.1 million from the automatic conversion of outstanding promissory notes, as described below. These transactions, which were completed on January 12, 2016, are referred to as the 2016 Offering. The Stock Purchase Agreement contains customary representations, warranties and covenants by each of us and the purchasers.

The number of shares sold pursuant to the Stock Purchase Agreement included an aggregate of 6,081,858 shares that were issued upon the automatic conversion of our 6% Unsecured Convertible Promissory Notes (the "Notes"). The Notes were originally issued in the principal amount of $2.1 million on October 21, 2015, and such principal amount and all accrued interest were converted into shares in accordance with their terms.

**Registration Rights Agreement**

*The following description is qualified in its entirety by the terms and conditions set forth in the registration rights agreement with respect to the 2016 Offering incorporated by reference to the registration statement that contains this prospectus hereto, which we refer to as the Registration Rights Agreement. The following description may not contain all the information with respect to such registration rights important to you. We encourage you to read the Registration Rights Agreement.*

In connection with the entry into the Stock Purchase Agreement, and as contemplated thereby, on January 12, 2016, we entered into a Registration Rights Agreement with the purchasers. Pursuant to the terms of the Registration Rights Agreement, we agreed to file, within 60 days following the date of the Registration Rights Agreement, or by March 12, 2016, a registration statement under the Securities Act covering the resale of the shares of common stock issued pursuant to the Stock Purchase Agreement, and to cause such registration statement to be declared effective by the SEC as soon as practicable thereafter, but not later than 120 days following the date of the Registration Rights Agreement, or by May 11, 2016. If such registration statement was not declared effective by the SEC by such date, we agreed to pay liquidated damages to the investors in the amount of 1% of each purchaser's aggregate investment amount per month until the registration statement is declared effective, subject to a maximum of 10% of each purchaser's aggregate investment amount. We are required to maintain the effectiveness of the registration statement until all of the shares covered thereby are sold or may be sold pursuant to Rule 144 under the Securities Act without

volume or manner-of-sale restrictions and without the requirement that we be in compliance with the current public information requirements of Rule 144. The registration statement of which this prospectus is a part registers the resale of the shares of our common stock contemplated by the Registration Rights Agreement and was declared effective on April 18, 2016.

**USE OF PROCEEDS**

We will receive none of the proceeds from the sale of the shares by the selling stockholders.

**SELLING STOCKHOLDERS**

This prospectus covers the resale by the selling stockholders identified below of 21,153,997 shares of our common stock, all of which were issued and sold to the selling stockholders in connection with our 2016 Offering. The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of April 18, 2016, and after giving effect to this offering, except as otherwise referenced below.

| Selling Stockholder | **Shares beneficially owned Before offering (1)** | **Number of outstanding shares offered by selling stockholder** | **Beneficial ownership after offering (1)** | |
|---|---|---|---|---|
| | | | **Number of shares** | Percent |
| Abel G. Halpern (2) | 1,007,950 | 715,000 | 292,950 | * |
| Alexander A. Zukiwski (3) | 1,543,315 | 144,806 | 1,398,509 | 3.3 |
| Arie S. Belldegrun M.D. Inc. Profit Sharing Plan (4) | 8,567,556 | 1,448,062 | 6,405,209 | 13.7 |
| Bonderman Family Limited Partnership (5) (6) | 5,729,305 | 2,142,857 | 3,586,448 | 8.2 |
| Commercial Street Capital LLC (7) | 7,600,982 | 2,876,633 | 4,724,349 | 10.6 |
| David M. Tanen Revocable Trust (8) | 662,854 | 362,015 | 300,839 | * |
| Green Fields Offshore, Inc. (9) | 3,506,448 | 1,000,000 | 2,506,448 | 5.7 |
| Jay Moorin (10) | 655,170 | 642,858 | 12,312 | * |
| Joshua A. Kazam Irrevocable Trust (11) | 392,650 | 362,015 | 30,635 | * |
| Leumi Overseas Trust Corporation Limited as Trustee of the BTL Trust (4) | 8,567,556 | 714,285 | 6,405,209 | 13.7 |
| Malkev Capital LP (12) | 285,714 | 285,714 | - | - |
| A.I. Montserrat Global Fund (13) | 2,236,485 | 434,418 | 1,367,649 | 3.2 |
| Montserrat Healthcare Fund , L.P. (13) | 2,236,485 | 434,418 | 1,367,649 | 3.2 |
| OPKO Health, Inc. (14) | 3,105,249 | 714,285 | 2,390,964 | 5.5 |
| Perceptive Life Sciences Master Fund Ltd. (5) (15) | 12,415,496 | 1,235,714 | 11,179,782 | 9.9 |
| Pontifax (Cayman) II L.P. (16) | 4,872,169 | 707,868 | 3,424,107 | 7.8 |

| | | | | |
|---|---|---|---|---|
| Pontifax (Israel) II - Individual Investors L.P. (16) | 4,872,169 | 206,986 | 3,424,107 | 7.8 |
| Pontifax (Israel) II L.P. (16) | 4,872,169 | 533,208 | 3,424,107 | 7.8 |
| Quantum Partners LP (5) (17) | 14,885,565 | 2,071,428 | 12,814,137 | 9.9 |
| Ronald I. Dozoretz (18) | 3,039,469 | 2,142,857 | 896,612 | 2.1 |
| Sabby Healthcare Master Fund, Ltd. (5) (19) | 3,320,873 | 1,000,000 | 2,320,873 | 5.3 |
| Stuart & Toni Holden Family Trust (20) | 71,428 | 71,428 | - | - |
| Titan Perc, Ltd. (21) | 192,857 | 192,857 | - | - |
| Uzi Zucker (22) | 1,162,812 | 714,285 | 448,527 | 1.1 |
| TOTALS | | 21,153,997 | | |

* denotes less than 1%

(1) Based upon 41,562,613 issued and outstanding shares of our common stock as of April 18, 2016. Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the selling stockholder has sole or shared voting power or investment power, and also any shares which the selling stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the selling stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) In addition to the shares offered hereby, beneficial ownership also includes 92,524 shares of our common stock, 122,546 shares issuable upon the exercise of 2012 Series A Warrants, and 77,880 shares issuable upon the exercise of 2013 Series D Warrants.

(3) Dr. Zukiwski is our Chief Executive Officer and Chief Medical Officer and a member of our board of directors. In addition to the shares offered hereby, beneficial ownership also includes 117,026 shares of our common stock, 183,822 shares issuable upon the exercise of 2012 Series A Warrants, 77,880 shares issuable upon the exercise of 2013 Series D Warrants, and 1,019,781 shares issuable upon the exercise of stock options.

(4) In addition to the shares offered hereby, beneficial ownership also includes: (i) 3,115 shares of our common stock and 3,227,861 shares issuable upon the exercise of stock options held by Arie Belldegrun, M.D.; (ii) 379,294 shares of our common stock, 428,920 shares issuable upon the exercise of 2012 Series A Warrants, and 350,467 shares issuable upon the exercise of 2013 Series D Warrants held by Arie and Rebecka Belldegrun as Trustees of the Belldegrun Family Trust dated February 18, 1994; (iii) 143,810 shares of our common stock and 194,702 shares issuable upon the exercise of 2013 Series D Warrants held by Leumi Overseas Trust Corporation Limited ("Leumi") as Trustee of the BTL Trust; (iv) 254,887 shares of our common stock, 367,646 shares issuable upon the exercise of 2012 Series A Warrants, and 194,702 shares issuable upon the exercise of 2013 Series D Warrants held by Leumi as Trustee of the Tampere Trust; (v) 100,481 shares of our common stock and 245,096 shares issuable upon the exercise of 2012 Series A Warrants held by the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan; and (vi) 174,644 shares of our common stock, 183,822 shares issuable upon the exercise of 2012 Series A Warrants, and 155,762 shares issuable upon the exercise of 2013 Series D Warrants held by MDRB Partnership, L.P. ("MDRB"). Dr. Belldegrun, who serves as Chairman of our board of directors, is a beneficiary of each of the BTL Trust and the Tampere Trust and is the managing partner of MDRB. Dr. Belldegrun holds voting and/or dispositive power over the shares held by MDRB and the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan. Richard J. Guillaume and John Le M Germain, directors of Leumi Overseas Trust Corporation Limited ("Leumi"), hold voting and/or dispositive power over the shares held by Leumi as trustee of each of the BTL Trust and the Tampere Trust.

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(5) Notwithstanding the number of shares of our common stock shown as beneficially owned by the selling stockholder in the table above, the warrants held by the selling stockholder provide that the selling stockholder may not exercise such warrants to the extent that the selling stockholder would beneficially own in excess of 9.99% of our outstanding common stock immediately after giving effect to such exercise.

(6) Wildcat Capital Management, LLC ("WCM"), a registered investment advisor, has dispositive and voting power over the shares held by Bonderman Family Limited Partnership pursuant to the terms of an investment management agreement. Leonard Potter is President and Chief Investment Officer of WCM. In addition to the shares offered hereby, beneficial ownership also includes 1,250,000 shares of our common stock and 2,336,448 shares issuable upon the exercise of 2013 Series D Warrants.

(7) Steven Ruchefsky, President of Commercial Street Capital, LLC, is a director of Arno and holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes (i) 1,596,272 shares of our common stock, 1,531,861 shares issuable upon the exercise of 2012 Series A Warrants, and 1,285,046 shares issuable upon the exercise of 2013 Series D Warrants held by Commercial Street Capital, LLC, and (ii) 311,170 shares of our common stock issuable upon the exercise of stock options held by Mr. Ruchefsky.

(8) Gregory Kiernan, the trustee of the David M. Tanen Revocable Trust, holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes (i) 171,712 shares of our common stock and 110,436 shares issuable upon the exercise of stock options held by Mr. Tanen, and (ii) 18,691 shares held by Mr. Tanen's minor children. Mr. Tanen is a member of our board of directors.

(9) Anton Linderum holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes 100,480 shares of our common stock, 245,096 shares issuable upon the exercise of 2012 Series A Warrants, 753,138 shares issuable upon the exercise of 2013 Series C Warrants, and 1,407,734 shares issuable upon the exercise of 2013 Series D Warrants.

(10) In addition to the shares offered hereby, beneficial ownership also includes 12,312 shares issuable upon the exercise of stock options. Mr. Moorin is a member of our board of directors.

(11) Gregory Kiernan, the trustee of the Joshua A. Kazam Irrevocable Trust, holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes 30,635 shares issuable upon the exercise of 2012 Series A Warrants.

(12) Henry Swieca holds voting and/or dispositive power over the shares held by the selling stockholder.

(13) Dr. Raj Mehra holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes (i) 376,804 shares of our common stock and 919,117 shares issuable upon the exercise of 2012 Series A Warrants held by A.I. Montserrat Global Fund, and (ii) 25,000 shares of our common stock and 46,728 shares issuable upon the exercise of 2013 Series D Warrants held by Auriga Global Investors SV, SA.

(14) Steven Rubin holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes 833,333 shares of our common stock and 1,557,631 shares issuable upon the exercise of 2013 Series D Warrants. Pursuant to an agreement with us dated October 29, 2013, and in connection with its investment in our 2013 private placement of common stock and warrants, OPKO Health, Inc. ("OPKO") has the right to designate one person as a non-voting observer to our board of directors and has a right of first negotiation with respect to certain strategic transactions that we may wish to pursue, in each case for as long as OPKO continues to hold at least 3% of our outstanding common stock determined on a fully-diluted basis.

(15) Joseph Edelman holds voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes 2,034,721 shares of our common stock, 3,676,470 shares issuable upon the exercise of 2012 Series A Warrants, 1,562,343 shares issuable upon the exercise of 2013 Series C Warrants, and 3,906,248 shares issuable upon the exercise of 2013 Series D Warrants.

(16) Tomer Kariv and Ran Nussbaum hold voting and/or dispositive power over the shares held by the selling stockholder. Mr. Kariv is a director of Arno. In addition to the shares offered hereby, beneficial ownership also includes: (i) 639,459 shares of our common stock, 599,064 shares issuable upon the exercise of 2012 Series A Warrants, and 380,714 shares issuable upon the exercise of 2013 Series D Warrants held by Pontifax (Cayman) II L.P., (ii) 186,982 shares of our common stock, 175,170 shares issuable upon the exercise of 2012 Series A Warrants, and 111,323 shares issuable upon the exercise of 2013 Series D Warrants held by Pontifax (Israel) II - Individual Investors L.P., (iii) 481,680 shares of our common stock, 451,252 shares issuable upon the exercise of 2012 Series A Warrants, and 286,777 shares issuable upon the exercise of 2013 Series D Warrants held by Pontifax (Israel) II L.P., and (iv) 111,686 shares of our common stock issuable upon the exercise of stock options held by Mr. Kariv.

(17) Soros Fund Management LLC ("SFM") serves as principal investment manager to Quantum Partners LP. As such, SFM has been granted investment discretion over portfolio investments, including the shares reported in the table above, held for the account of Quantum Partners LP. George Soros serves as Chairman of SFM and Robert Soros serves as President and Deputy Chairman of SFM. In addition to the shares offered hereby, beneficial ownership also includes 2,001,987 shares of our common stock, 3,982,840 shares issuable upon the exercise of 2012 Series A Warrants, 2,139,750 shares issuable upon the exercise of 2013 Series C Warrants, and 4,689,560 shares issuable upon the exercise of 2013 Series D Warrants.

(18) In addition to the shares offered hereby, beneficial ownership also includes 312,500 shares of our common stock and 584,112 shares issuable upon the exercise of 2013 Series D Warrants held by FHC Stock Holdings, LLC.

(19) Sabby Management, LLC serves as the investment manager of Sabby Healthcare Master Fund, Ltd. Hal Mintz is the manager of Sabby Management, LLC. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the shares offered hereby except to the extent of its pecuniary interest therein. In addition to the shares offered hereby, beneficial ownership also includes 204,900 shares of our common stock, 1,531,861 shares issuable upon the exercise of 2012 Series A Warrants, and 584,112 shares issuable upon the exercise of 2013 Series D Warrants.

(20) Stuart Holden holds voting and/or dispositive power over the shares held by the selling stockholder.

(21) Joseph Edelman holds voting and/or dispositive power over the shares held by the selling stockholder.

(22) In addition to the shares offered hereby, beneficial ownership also includes 170,219 shares of our common stock, 122,546 shares issuable upon the exercise of 2012 Series A Warrants, and 155,762 shares issuable upon the exercise of 2013 Series D Warrants.

**PLAN OF DISTRIBUTION**

We are registering the shares offered by this prospectus on behalf of the selling stockholders. The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. To the extent any of the selling stockholders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling stockholders under this prospectus.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
-

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

- a combination of any such methods of sale; and

- any other method permitted pursuant to applicable law.

The selling stockholders may also sell the shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the shares or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume. The selling stockholders may also sell shares short and deliver these shares to close out their short positions, or loan or pledge the shares to broker-dealers that in turn may sell these shares. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the shares. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. The selling stockholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) the date on which all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of our securities by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

**Shares Eligible For Future Sale**

Upon completion of this offering, there will be 41,562,613 shares of our common stock issued and outstanding. The shares purchased in this offering will be freely tradable without registration or other restriction under the Securities Act, except for any shares purchased by an "affiliate" of our company (as defined in the Securities Act).

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of such rule. Rule 144 governs resale of "restricted securities" for the account of any person (other than us), and restricted and unrestricted securities for the account of an "affiliate" of ours. Restricted securities generally include any securities acquired directly or indirectly from us or our affiliates, which were not issued or sold in connection with a public offering registered under the Securities Act. An affiliate of ours is any person who directly or indirectly controls us, is controlled by us, or is under common control with us. Our affiliates may include our directors, executive officers, and persons directly or indirectly owing 10% or more of our outstanding common stock. In general, under Rule 144, a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale, and who has beneficially owned restricted securities for at least six months would be entitled to sell those shares, subject to the requirements of Rule 144 regarding publicly available information about us. Affiliates may only sell in any three month period that number of shares that does not exceed the greater of 1 percent of the then-outstanding shares of our common stock or the average weekly trading volume of our shares of common stock in the over-the-counter market during the four calendar weeks preceding the sale. However, because we were formerly a "shell company," in order for the holders of our restricted securities to resell their shares in reliance upon Rule 144, we are required to have been subject to the public reporting requirements of the Exchange Act for at least 90 days, and to have filed all reports required to be filed during the 12 months preceding such sale (or such shorter period that we were required to file such reports).

Following the date of this prospectus, we cannot predict the effect, if any, that sales of our common stock or the availability of our common stock for sale will have on the market price prevailing from time to time. Nevertheless, sales by existing stockholders of substantial amounts of our common stock could adversely affect prevailing market prices for our stock.

## DESCRIPTION OF CAPITAL STOCK

### General

Our amended and restated certificate of incorporation, as amended, authorizes us to issue 535,000,000 shares of capital stock, par value $0.0001 per share, comprised of 500,000,000 shares of common stock and 35,000,000 shares of preferred stock.

As of the date of this prospectus, we have issued and outstanding approximately:

- 41,562,613 shares of our common stock,
- options to purchase 11,010,805 shares of our common stock at exercise prices ranging from $0.30 to $19.38 per share, and
- warrants to purchase 47,065,302 shares of our common stock at exercise prices ranging from $0.01 to $2.64 per share.

### Common Stock

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. Upon our liquidation, dissolution or winding down, holders of our common stock will be entitled to share ratably in all of our assets that are legally available for distribution, after payment of all debts and other liabilities. The holders of our common stock have no preemptive, subscription, redemption or conversion rights.

Holders of our common stock are entitled to receive such dividends, as the board of directors may from time to time declare out of funds legally available for the payment of dividends. We seek growth and expansion of our business through the reinvestment of profits, if any, and do not anticipate that we will pay dividends in the foreseeable future.

### Authority to Issue Stock

Our board of directors has the authority to issue the authorized but unissued shares of our common stock without action by the shareholders. The issuance of such shares would reduce the percentage ownership held by current shareholders.

Our amended and restated certificate of incorporation authorizes the issuance of up to 35,000,000 shares of preferred stock, none of which are issued or currently outstanding. Our board of directors has the authority to fix and determine the relative rights and preferences of up to 35,000,000 preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that is senior to our common stock and that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption to such shares, together with other rights, none of which will be afforded holders of our common stock.

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

### Market Information

Our common stock is currently eligible for trading on the OTCQB tier of the OTC Markets under the symbol "ARNI." The historical trading of our common stock has been extremely limited and sporadic. Set forth below are the high and low sales prices for our common stock during each quarter within the last two fiscal years, as reported by the OTCQB. The quotations reflect inter-dealer prices, without retail markup, markdown, or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions.

| Quarter Ended | High | Low |
|---|---|---|
| March 31, 2014 | $3.00 | $1.96 |
| June 30, 2014 | $2.30 | $1.40 |
| September 30, 2014 | $1.78 | $1.24 |
| December 31, 2014 | $1.35 | $0.43 |
| March 31, 2015 | $0.68 | $0.55 |
| June 30, 2015 | $1.15 | $0.54 |
| September 30, 2015 | $0.62 | $0.21 |
| December 31, 2015 | $0.48 | $0.18 |

### Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of April 18, 2016, we had approximately 300 holders of record of common stock, not including those held in "street name."

### Dividends

We have never declared or paid a dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

### Securities Authorized for Issuance under Equity Compensation Plans

We grant stock options and other equity incentive awards pursuant to our 2005 Stock Option Plan (the "Plan"), which has been approved by our stockholders. The following table sets forth certain information as of December 31, 2015 with respect to the Plan:

| Plan category | Number of Securities to be Issued Upon Exercise of Outstanding Options (A) | Weighted-Average Exercise Price of Outstanding Options (B) | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C) |
|---|---|---|---|
| Equity compensation plans approved by security holders: | | | |
| 2005 Stock Option Plan | 7,027,658 | $ 2.57 | 4,087,657 |
| Equity compensation plans not approved by stockholders: | | | |
| None | — | — | — |
| Total | 7,027,658 | $ 2.57 | 4,087,657 |

**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and plan of operations should be read in conjunction with the financial statements and the notes to those statements included in this prospectus. This discussion includes forward-looking statements that involve risk and uncertainties. As a result of many factors, such as those set forth in this prospectus under "Risk Factors," actual results may differ materially from those anticipated in these forward-looking statements.*

**Company Overview**

We are an early-stage company focused on developing innovative products for the treatment of cancer and other life threatening diseases. We currently have exclusive worldwide rights to three innovative clinical stage compounds with unique mechanisms of action that have the potential to be first-in-class therapeutics. The following is a summary of our product development pipeline:

- ***Onapristone*** – We are currently developing onapristone, an oral anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in patients with breast cancer. Onapristone appears to have a unique ability to block the activation of the progesterone receptor and inhibit tumor growth. In connection with the development of onapristone, we have engaged Leica Biosystems to develop an immunohistochemistry based diagnostic test to identify tumors with the activated form of the progesterone receptor (APR), which is intended to identify patients more likely to benefit from treatment with onapristone. Additional biomarker development is ongoing to develop a diagnostic test to identify progesterone receptor (PR) in tumor types other than breast cancer.

In April 2014, we enrolled the first patient in a Phase I/II clinical trial of onapristone in men with advanced castration-resistant prostate cancer, or CRPC, after failure of abiraterone or enzalutamide. This study is currently being conducted at three sites in the United Kingdom, led by the Royal Marsden NHS Foundation Trust in London. The randomized, open-label trial is designed to evaluate the safety and anti-cancer activity of onapristone in the defined patient population. The Phase I component of the study evaluated onapristone extended-release tablet formulations in five dose levels (10-50 mg, twice daily) in patients with prostate cancer and has completed enrollment. The protocol has been amended to study the combination of onapristone plus abiraterone in a Phase I setting with an expansion phase. In addition, the protocol also includes a Phase II cohort of patients that will be enrolled to gain additional understanding of the onapristone as a potential treatment in men with CRPC. The Phase II aspect of the study includes; a component that will evaluate the combination of onapristone plus abiraterone acetate in men who have had evidence of progression of disease while on abiraterone acetate. Another component of this Phase II aspect of the study will further evaluate the safety profile and potential anti-cancer activity of single agent onapristone in men with advanced CRPC after failure of abiraterone or enzalutamide. In accordance with the modified Phase II study protocol, study subjects will be evaluated for whether their tumors express PR/APR or the T878A androgen receptor

mutation, which may help identify patients who are more likely to respond to onapristone in future studies. Screening of patients under the amended study protocol began in the first quarter of 2016 and the Phase II study will include approximately 75 patients.

In addition, in December 2014, we enrolled the first patient in the expansion phase of our ongoing Phase I/II clinical trial evaluating onapristone in women with progesterone receptor (PR) expressing tumors. The protocol was subsequently amended to include a formal Phase II study in patients with recurrent or metastatic endometrioid tumors that have been shown to express PR, and who have received no more than one prior chemotherapy and no prior hormone therapy. Patients in the Phase II component of the study received 50mg of extended release onapristone twice daily, the dose determined by an independent data review committee to be safely administered to patients based on the results of the Phase I component of this study. The study incorporated a diagnostic test targeting women with tumors expressing APR, which was intended to select those patients more likely to respond to onapristone treatment. In April 2016, we determined to close this clinical trial in order to focus our resources on our prostate cancer program.

***AR-12 and analogues –*** AR-12 was initially being developed as an orally available agent which demonstrated to inhibit multiple different kinase targets. We believe AR-12 may also cause malignant cell death through the induction of stress in the endoplasmic reticulum and recent work has demonstrated that AR-12 inhibits various molecular protein chaperones including GRP78, HSP70, HSP90 and HSP27. We have completed a Phase I clinical trial of AR-12 in adult patients with advanced or recurrent solid tumors or lymphoma using the original non optimized formulation of AR-12. Subsequently, an improved formulation of AR-12 that has been shown to substantially increase bioavailability in preclinical models has been developed. Based on additional pre-clinical research conducted on AR-12, we are currently pursuing various opportunities with the potential for securing non-dilutive funding, via government and philanthropic agency grants and contracts, for further research into the potential use of AR-12 as an anti-microbial agent. In April 2015, the EMA granted two orphan drug designations for AR-12 for the treatment of cryptococcosis and tularaemia. Cryptococcosis is an infectious disease of the lungs caused by the fungus *Cryptococcus neoformans* and is one of the most common life-threatening fungal infections in people with AIDS. Tularaemia is an infection which can be spread from animals to humans that is caused by the bacterium *Francisella tularensis* and is a Category A Priority Pathogen on the National Institute of Allergy and Infectious Disease (NIAID) list of Biodefense and Emerging Infectious Diseases. A CRADA is in place with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) for the evaluation of AR-12 and four analogues against pathogens of biodefense interests. Other analogues of AR-12 such as AR-13 are being investigated for activity against certain microbial pathogens through a number of collaborations.

- ***AR-42 –*** AR-42 is being developed as an orally available, broad spectrum inhibitor of both histone and non-histone deacetylation proteins, or Pan-DAC, which play an important role in the regulation of gene expression, cell growth and survival. AR-42 recently completed an investigator-initiated dose escalation clinical study with an expansion phase in adult subjects with relapsed or refractory hematological malignancies (multiple myeloma, chronic lymphocytic leukemia (CLL), or lymphoma) and solid tumors. The recommended Phase II dose, or RP2D, in patients with hematological malignancies has been determined and the expansion phase of the program has been completed. The protocol has been amended to include a separate solid tumor dose escalation cohort and expansion phase. The solid tumor component of the study has been completed. We also supported an investigator initiated Phase I study of AR-42 in combination with decitabine in patients with hematological malignancies that was initiated during the third quarter of 2013. The FDA has granted two orphan drug designations for AR-42 for the treatment of meningioma and the treatment of schwannoma of the central nervous system. Meningioma and schwannoma are rare, benign tumors that can present in different locations within the brain and the spinal cord and may cause substantial morbidity for those affected individuals. Additionally, AR-42 has been granted three orphan drug designations by the European Medicines Agency, or EMA, for the treatment of neurofibromatosis type 2 (NF2), the treatment of meningioma and the treatment of schwannoma. NF2 is a rare genetic disorder characterized by the growth of noncancerous tumors in the brain and spinal cord, juvenile cataracts, and neurofibromas of the skin. Additional investigator sponsored clinical trials of AR-42 are currently underway or being planned.

We have no product sales to date and we will not generate any product revenue until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety or other issues during the course of developing our product candidates, we do not expect to complete the development of a product candidate for several years, if ever. To date, almost all of our development expenses have been incurred on each of our product candidates: Onapristone, AR-12, AR-42 and AR-67 (a compound we are no longer developing). As we proceed with the clinical development of our product candidates, primarily focusing our resources on onapristone, our research and development expenses will further increase. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. To date, our major sources of working capital have been proceeds from private and public sales of our common and preferred stock and debt financings.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, costs related to obtaining and maintaining our product license agreements, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our R&D costs as they are incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, accounting, legal and other professional fees, business development expenses, rent, business insurance and other corporate expenses.

Our results include non-cash compensation expense as a result of the issuance of stock options. We expense the fair value of stock options over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial performance and product development. Stock-based compensation expense is included in the respective categories of expense in the statements of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

**Results of Operations**

*General and Administrative Expenses*. G&A expenses for the years ended December 31, 2015 and 2014 were approximately $4.8 million and $6.7 million, respectively. This decrease of approximately $1.9 million over 2014 is primarily attributable to decreased compensation expense of approximately $1.5 million consisting of a decrease of approximately $0.9 million in stock compensation expense, lower severance of $0.4 million related to the departure of our previous CEO in 2014 and reduced spending on professional fees of $0.3 million.

*Research and Development Expenses*. R&D expenses for the years ended December 31, 2015 and 2014 were approximately $8.7 million and $14.8 million, respectively. The decrease of approximately $6.1 million over 2014 was primarily due to decreased in spending our lead product candidate, onapristone. Total direct onapristone development costs for the year ended December 31, 2015 were approximately $5.8 million compared to approximately $11.6 million for the year ended December 31, 2014. This decrease of approximately $5.8 million over the same period of 2014 is primarily due to decreased spending of $5.5 million on pre-clinical and non-clinical research activities that supported the initiation of the Phase I/II clinical trials and companion diagnostic development program in 2014 and reduced spending on clinical trials of $0.3 million. We also incurred lower compensation costs of $0.5 million in 2015 over the same period of 2014.

The following table summarizes our R&D expenses incurred for preclinical support, contract manufacturing of clinical supplies, clinical trial services provided by third parties and milestone payments for in-licensed technology for the years ended December 31, 2015 and 2014, as well as the cumulative amounts since we began R&D development through December 31, 2014. The table also summarizes unallocated costs, which consist of personnel, facilities, stock based compensation and other costs not directly allocable to development programs. The amounts stated are expressed in thousands.

| | Year Ended December 31, | | Cumulative amounts during development |
|---|---|---|---|
| | 2015 | 2014 | |
| Onapristone | $ 5,808 | $ 11,582 | $ 31,787 |
| Other R&D Projects | 1,149 | 736 | 25,889 |
| Unallocated R&D | 1,696 | 2,522 | 16,140 |
| Total | $ 8,653 | $ 14,840 | $ 73,816 |

Our expenditures on current and future clinical development programs are expected to be substantial and to increase particularly in relation to our available capital resources. Based on our current development plans, during the fiscal year 2016 we anticipate external development costs to be approximately $4.8 million for onapristone and $0.6 for other research and development projects. However, these planned expenditures are subject to many uncertainties, including the availability of necessary capital, the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, it is very difficult to accurately predict the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;

- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs and timing of manufacturing our drug candidates; and
- the costs, requirements, timing of, and the ability to secure regulatory approvals.

*Interest Income*. Interest income for the years ended December 31, 2015 and 2014 was $7,658 and $41,954, respectively. The decrease in interest income over 2014 is due to lower average cash balance levels during 2015 as compared to 2014.

*Interest Expense*. Interest expense for the years ended December 31, 2015 and 2014 was approximately $28,403 and $143, respectively. The increase in interest expense in 2015 over 2014 is the result of interest expense and amortization of financing costs associated with convertible notes issued in the fourth quarter of 2015.

The following table illustrates the components of total interest expense for 2015 and 2014. The amounts stated are expressed in thousands.

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Interest expense on 2015 convertible notes | $ 25 | $ - |
| Amortized financing fees | 2 | - |
| Interest expense on capital lease obligation | 1 | - |
| | $ 28 | $ - |

*Other Income (Expense).* Other income for the year ended December 31, 2015 was approximately $1.9 million compared to an income of $29.2 million for the year ended December 31, 2014. The change in 2015 over 2014 is related to noncash adjustments to the warrant liability primarily driven by our decreased stock price, the expiration of certain warrants and reduced amount of time until the remaining warrants expire.

**Liquidity and Capital Resources**

The following tables summarize our liquidity and capital resources as of and for each of the last two fiscal years, and are intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

| | Year Ended December 31, | |
|---|---|---|
| Liquidity and capital resources | 2015 | 2014 |
| Cash and cash equivalents | $ 67 | $ 7,948 |
| Working capital | (3,903) | 6,049 |
| Stockholders' deficit | (8,624) | (589) |

| | Year Ended December 31, | |
|---|---|---|
| Cash flow data | 2015 | 2014 |
| Cash used in: | | |
| Operating activities | $ (9,966) | $ (18,806) |
| Investing activities | - | (20) |
| Financing activities | 2,084 | 0 |
| Net decrease in cash and cash equivalents | $ (7,882) | $ (18,826) |

Our total cash resources as of December 31, 2015 were approximately $0.1 million compared to approximately $7.9 million as of December 31, 2014. As of December 31, 2015, we had approximately $9.0 million in liabilities (of which approximately $4.8 million represented non-cash derivative liabilities), and a deficit of approximately $3.9 million of net working capital. We realized a net loss of approximately $11.5 million and had negative cash flow from operating activities of approximately $10.0 million for the year ended December 31, 2015. As we continue to develop our product candidates, we expect to incur substantial and increasing losses, which will continue to generate negative net cash flows from operating activities as we expand our technology portfolio and engage in further research and development activities, particularly conducting human clinical trials.

In October 2015, we received gross proceeds of $2.1 million from our sale and issuance of 6% Unsecured Convertible Promissory Notes (the "Notes") pursuant to a note purchase agreement among us and several purchasers identified in such agreement. The Notes, which had a maturity date of October 21, 2016, accrued interest at the rate of six percent per annum. On January 12, 2016, the entire $2.1 million principal amount of the Notes and $28,652 of accrued interest thereunder were automatically converted into an aggregate of 6,081,858 shares of our common stock in connection with the 2016 Offering, as described below.

On January 12, 2016, we received gross proceeds of approximately $7.4 million, including approximately $2.1 million from the automatic conversion of the Notes and approximately $5.3 million in cash, from our sale and issuance of common stock pursuant to a stock purchase agreement among us and several purchasers identified in such agreement. See "Description of 2016 Offering."

From inception through the date of this prospectus, we have financed our operations through private sales of our equity and debt securities. As we have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to continue to fund our research and development, including our long-term plans for clinical trials and new product development, as well as to fund operations generally. We will seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Based on our current development plans, we believe our existing cash resources, including the $2.1 million proceeds from the sale of the Notes in October 2015 and the proceeds from the 2016 Offering, are sufficient to fund our operations through approximately May 2016. However, based on the various options for future clinical studies of onapristone, AR-12 and AR-42, our projected cash needs are difficult to predict. In addition, there are other factors which may also cause our actual cash requirements to vary materially, including changes in the focus and direction of our research and development programs; the acquisition and pursuit of development of new product candidates; competitive and technical advances; costs of commercializing any of the product candidates; and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. If we are unable to raise additional funds when needed, we may not be able to continue development and regulatory approval of our products, and we could be required to delay, scale back or eliminate some or all of our research and development programs and we may need to wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on our business and may result in a loss of your entire investment in our common stock.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress and results of our research activities;
- the costs of hiring additional full-time personnel;
- the number and scope of our research programs;
- the progress and results of our pre-clinical and clinical development activities;
- the costs and timing of manufacturing our drug candidates;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements; and
- the cost involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the cost and timing of regulatory approvals.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments that might result from the inability of the Company to continue as a going concern.

**Off -Balance Sheet Arrangements**

There were no off-balance sheet arrangements as of December 31, 2015.

**Critical Accounting Policies and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

***Research and Development Expenses and Accruals***

R&D expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, costs related to obtaining and maintaining our product licenses, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations, or CROs, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CROs and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimate of the degree of completion of the event or events specified in the specific contract.

No adjustments for material changes in estimates have been recognized in any period presented.

***Stock-Based Compensation***

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants. We have issued stock options to employees, directors, consultants and Scientific Advisory Board members under our 2005 Stock Option Plan, as amended.

We expense the fair value of employee stock-based compensation over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, the risk-free interest rate and the estimated rate of forfeitures of

unvested stock options.

Stock options or other equity instruments to non-employees (including consultants and all members of our Scientific Advisory Board) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in the respective categories of expense in the Statements of Operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

***Convertible Debentures and Warrant Liability***

We account for the warrants issued in connection with the 2013 private placement, for the convertible debentures and warrants issued in connection with the 2012 private placement and for the warrants issued in connection with the 2010 private placement in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that we classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The fair value of warrants issued by us, in connection with private placements of securities, has been estimated using a Monte Carlo simulation model. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of our future expected stock prices and minimizes standard error.

***Recent Accounting Pronouncements***

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, “Presentation of Financial Statements-Going Concern (Topic 205-40)” (“ASU 2014-15”). Under the standard, management is required to evaluate for each annual and interim reporting period whether it is probable that the entity will not be able to meet its obligations as they become due within one year after the date that financial statements are issued, or are available to be issued, where applicable. ASU 2014-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The Company will be evaluating the impact, if any, that the standard will have on its financial condition, results of operations, and disclosures in the near future.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, “Interest- Imputation of Interest (Subtopic 835-30)” (“ASU 2015-03”). This standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those years. Accordingly, the standard is effective for the Company on December 15, 2015. The Company adopted ASU 2015-03 as for the fiscal year 2015 and has reported financing costs as a direct reduction from the carrying amount of convertible notes. The Company’s addition of the standard did not have a material impact on its financial condition, results of operations and disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, “Balance Sheet Classification of Deferred Taxes” (“ASU 2015-17”). The new standard requires all companies to prospectively classify all deferred tax assets and liabilities as noncurrent on the balance sheet. ASU 2015-17 will be effective for public entities on January 1, 2017. However, early adoption is permitted. The Company is evaluating the potential impact of adopting this standard on its financial statements.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, “Financial Instruments” (“ASU 2016-01”). Equity investments not accounted for under the equity method of accounting will be measured at fair value, with changes in fair value recognized in current earnings. ASU 2016-01 becomes effective for fiscal years beginning after December 15, 2017. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The Company does not believe the adoption of this standard will have a material impact on its financial statements, results of operations or related financial statement disclosures.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). Leasees will need to recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. ASU 2016-02 becomes effective for the Company on January 1, 2019, and early adoption is permitted upon issuance. The Company is evaluating the potential impact of adopting this standard on its financial statements.

**OUR BUSINESS**

**Overview**

We are an early stage enterprise focused on developing innovative products for the treatment of cancer and other life threatening diseases. The following table summarizes our product development pipeline:

| Product Candidate | Indications | Commercial Rights | Ongoing Studies / Status |
|---|---|---|---|
| Onapristone | Prostate, endometrial and breast cancer | Arno | Phase I/II clinical study in patients with castration resistant prostate cancer is ongoing in the U.K.<br><br>Development of a companion diagnostic to identify APR expressing tumors is ongoing pursuant to a collaboration with Leica Biosystems. |

| | | | |
|---|---|---|---|
| AR-12 | Solid tumors and hematological malignancies | Arno | Completed a Phase I clinical study in adult subjects with advanced or recurrent solid tumors or lymphoma. |
| AR-12 | Various anti-microbial targets | Arno | Pre-clinical. |
| | | | An investigator-initiated dose escalation study with an expansion phase has been completed at The Ohio State University in adult subjects with relapsed or refractory multiple myeloma, chronic lymphocytic leukemia or lymphoma, in addition to patients with solid tumors. |
| AR-42 | Hematological malignancies and solid tumors | Arno | Phase I investigator-initiated clinical study in combination with decitabine in patients with hematological malignancies has been completed. |
| | | | Phase 0 investigator-initiated study titled “Exploratory Evaluation of AR-42 Histone Deacetylase Inhibitor in the Treatment of Vestibular Schwannoma and Meningioma” is ongoing. |

**Corporate History; Merger Transactions**

On June 2, 2008, we were acquired by Laurier International, Inc., a Delaware corporation, in a “reverse” merger whereby a wholly-owned subsidiary of Laurier merged with and into Arno Therapeutics, with Arno Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of Laurier. In accordance with the terms of this merger, stockholders of Arno Therapeutics exchanged all of their shares of common stock of Arno Therapeutics for shares of Laurier common stock at a rate of approximately 0.25 shares of Laurier common stock for each share of Arno Therapeutics common stock. As a result of the issuance of the shares of Laurier common stock to the former Arno Therapeutics stockholders, following the merger the former stockholders of Arno Therapeutics held 95 percent of the outstanding common stock of Laurier, assuming the issuance of all shares underlying outstanding options and warrants. Upon completion of the merger, all of the former officers and directors of Laurier resigned and were replaced by the officers and directors of Arno Therapeutics. Additionally, following the merger Laurier changed its name to Arno Therapeutics, Inc.

**Oncology Overview**

According to the American Cancer Society, cancer is the second leading cause of death in the United States, surpassed only by heart disease, accounting for nearly one of every four deaths. According to the American Cancer Society, more than 1.6 million new cancer cases are expected to be diagnosed in 2015. According to a 2015 report by the American Cancer Society, the National Institutes of Health estimated direct costs for medical care for cancer related treatments in the United States in 2011 were $88.7 billion. With a 68% 5-year relative survival rate for all cancers from 2004-2010, according to the American Cancer Society, oncology remains a significant unmet medical need.

Pharmaceutical treatments are widely used to treat patients with cancer and are often used alongside surgery or radiation. Different types of cancers respond in unique ways to different drugs, and some tumors may not respond at all to particular therapies. In many cases, these treatments extend life by slowing the progression of the disease but become less effective over time as the cancer cells become resistant to a given therapy or a class of compounds with a particular mechanism of action. For this reason, there is a need to develop new agents, particularly those with novel mechanisms that can be added to the current arsenal of treatment options.

Many types of drugs are presently used to treat cancer, including cytotoxics, targeted agents, hormones, and biologics. According to a February 2012 report by Cowen & Co., the global cancer market was approximately $73.5 billion in 2011, of which cytotoxics accounted for $22.5 billion and targeted agents accounted for $33.2 billion.

Cytotoxics interfere with essential cellular processes in order to kill rapidly dividing cells, an effective approach for destroying cancer cells that remains prevalent despite the fact that these compounds can have significant side effects, particularly in rapidly dividing normal tissues such as those found in bone marrow and the gastrointestinal tract. By contrast, targeted agents attack cellular processes that are more prevalent in cancer cells than in normal tissues, and thus aim to simultaneously reduce side effects and improve efficacy.

Although there are many agents available to treat cancer, a number of factors contribute to determining which particular agent is administered to a patient. There is a considerable amount of overlap in the mechanisms of action of approved therapies, and in many cases, multiple drugs in a class are approved and in clinical use. The choice of a particular agent or class of agents is generally based on the results of empirical clinical trials in specific cancer indications, and a desire to treat the disease aggressively is balanced with considerations for the patient’s tolerance of the treatment and quality of life. These considerations highlight the need to develop therapies that not only improve anti-cancer efficacy but also improve patient convenience and reduce side effects.

**Product Development Pipeline**

***Onapristone***

*Overview*

Pursuant to a February 2012 license agreement with Invivis Pharmaceuticals, Inc., or Invivis, we have the exclusive rights worldwide to develop, and commercialize (other than in France), onapristone, an anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in patients with breast cancer. Onapristone appears to have a unique ability to block the activation of the progesterone receptor, which is believed to be the mechanism by which it may inhibit the growth of breast, endometrial and other cancers. Onapristone was originally being developed by Schering AG for potential use in the treatment of benign gynecological disorders (uterine leiomyoma, endometriosis), as a potential contraceptive and an anti-endocrine treatment of breast cancer. In previous published clinical studies, onapristone has demonstrated a 56% objective response rate as a first line “hormone” treatment of breast cancer. In connection with the development of onapristone, we intend to develop a companion diagnostic, or CDx, to identify patients’ tumors which express the progesterone receptor (PR) and the activated form of the progesterone receptor (APR) and therefore may be more likely to benefit from treatment with onapristone.

The hormones estrogen and progesterone play important roles in normal female reproductive physiology and the development of certain tissues/organs including the breast and uterus. These two naturally occurring hormones are also believed to play important roles in the development of certain female cancers (e.g. breast and endometrial) and the biologic effects of these two hormones make the estrogen and progesterone receptors important therapeutic targets. For example, chronic estrogen exposure unopposed by progesterone predisposes women to endometrial cancer, and the presence of estrogen or progesterone receptors in breast cancer tissues is predictive of response to anti-estrogen targeted therapies in women with breast cancer. Breast and endometrial cancers commonly express progesterone receptors but, to date, it has not been determined whether these receptors are functional and play a role in tumor growth. Prostate cancers can also express the progesterone receptor which may play a role in the development of androgen resistance. We believe a better diagnostic test may aide in selecting patients who are most likely to benefit from “hormone” treatments, including onapristone.

Onapristone is a type 1 anti-progestin. Researchers believe its mechanism of action to be a direct result of binding to the progesterone receptor and preventing the binding of the progesterone receptor to DNA, thereby substantially reducing or eliminating progesterone receptor induced gene transcription resulting in death of the malignant cell.

*Potential Advantages*

In prior publications, onapristone was reported to have a 56% objective response rate in patients with breast cancer as a first line endocrine treatment and a 49% clinical benefit rate in patients with breast cancer after failure of tamoxifen treatment. Our ongoing clinical studies of onapristone are intended to evaluate safety and efficacy which may provide women with endometrial cancer and men with castrate resistant prostate cancer an additional treatment option and allow a delay in the time for which patients may need chemotherapy treatment.

*Preclinical Studies*

We have completed a series of preclinical studies of onapristone since we acquired its rights in 2012. In these studies, 10 different breast cancer and endometrial cancer cell lines where characterized for hormone receptor status and the effect of various hormones and growth factors on proliferation and progesterone receptor status. When evaluating the effect of onapristone in the various culture conditions tested, cancer cell lines that expressed the activated form of the progesterone receptor, or APR, were found to respond to treatment with onapristone, but cell lines that did not express APR did not respond to onapristone treatment. We presented these findings in November 2012 at the 24th European Organization for Research and Treatment of Cancer symposium on Molecular Targets and Cancer Therapeutics in Dublin, Ireland and the April 2013 meeting of the American Association for Cancer Research in Washington, D.C.

*Clinical Development Plans and Activities*

In April 2014, we enrolled the first patient in a Phase I/II clinical trial of onapristone in men with advanced castration-resistant prostate cancer, or CRPC, after failure of abiraterone or enzalutamide. This study is currently being conducted at the Royal Marsden NHS Foundation Trust in London pursuant to approval of an Investigational Medicinal Product Dossier from the United Kingdom Health Authority, Medicines and Healthcare Products Regulatory Agency in January 2014. The randomized, open-label trial is designed to evaluate the safety and anti-cancer activity of onapristone in the defined patient population. The study will evaluate onapristone in extended-release tablet formulations in up to five dose levels (10-50 mg, twice daily) in patients with prostate cancer in which PR may be contributing to tumor progression. In accordance with the study protocol, study subjects will be evaluated for whether their tumors express PR and APR, which may help identify patients who are more likely to respond to onapristone. The Phase II cohort of patients will be enrolled to gain additional understanding of the onapristone safety profile and potential anti-cancer activity in men with advanced CRPC after failure of abiraterone or enzalutamide. The protocol has been amended to study the combination of onapristone plus abiraterone in a Phase II setting with short lead in dose escalation phase. In accordance with the modified Phase II study protocol, study subjects will be evaluated for whether their tumors express PR/APR or the T878A androgen receptor mutation, which may help identify patients who are more likely to respond to onapristone in future studies. Screening of patients under the amended study protocol began in the first quarter of 2016 and the Phase II study will include approximately 75

patients.

In addition, in December 2014, we enrolled the first patient in the expansion phase of our ongoing Phase I/II clinical trial evaluating onapristone in women with progesterone receptor expressing tumors. The protocol has been amended to include a formal Phase II study in patients with recurrent or metastatic endometrioid tumors that have been shown to express the progesterone receptor (PR), and who have received no more than one prior chemotherapy and no prior hormone therapy. Patients in the Phase II component of the study received 50 mg of extended release onapristone twice daily. The study also incorporated a diagnostic test, which was intended to select those patients most likely to respond to onapristone treatment. In April 2016, we determined to close this clinical trial in order to focus our resources on our prostate cancer program.

In January 2014, we enrolled the first patient in the Phase I dose escalation arm of the ongoing Phase I/II clinical trial, evaluating onapristone in post-menopausal women with progesterone receptor (PR) positive tumors, including breast, endometrial and other solid tumors. This Phase I trial was designed to identify the recommended Phase II dose and determine the overall safety profile of onapristone. Pursuant to the study protocol, this study evaluated onapristone in extended release and immediate release formulations across six dose levels (10-50 mg, twice daily, and 100 mg, once daily) to identify the recommended Phase II dose and gather data showing anticancer activity. This multi-site Phase I trial enrolled a total of 52 patients in France. In November 2014, we announced preliminary results for the study. At that time, the Phase I clinical trial had enrolled 48 patients with PR positive tumors in the dose escalation stage, including 28 patients with gynecologic malignancies and 19 patients with breast cancer. Prior to entering this study, these heavily pre-treated patients had previously received, on average, three chemotherapy treatment regimens and one hormone therapy regimen. In general, onapristone was well-tolerated without substantial dose limiting toxicities. A total of three patients experienced Grade 3 liver function test abnormalities associated with progression of liver metastases and discontinued onapristone treatment. None of these adverse events were deemed to be drug-related by an independent safety review committee. Currently, four patients from the dose escalation stage are still receiving onapristone therapy in the study. Five of the 48 patients enrolled in the dose escalation stage had been on study for less than eight weeks and were awaiting their first disease assessment evaluation. Of the 43 evaluable patients, one patient with serous ovarian cancer receiving 10mg twice daily of the extended release formulation had a durable partial response until week 40. In addition, 5 of 26 patients with gynecologic tumors and 2 of 16 patients with breast tumors had stable disease for greater than 24 weeks.

*Onapristone Companion Diagnostic Program*

A key aspect of our strategy to develop onapristone is to also develop a companion diagnostic, or CDx, that would identify whether a patient's tumor expresses PR and APR and therefore would be more likely to respond to treatment with onapristone. We and our research collaborators have identified an immunohistochemistry (IHC) technique for identifying activated progesterone receptors in breast cancer tumors. The initial findings were presented in December 2012 at the 35th Annual San Antonio Breast Cancer Symposium, with more mature data presented at the June 2013 annual meeting of the American Society of Clinical Oncology in Chicago, and in December 2013 at the 36th Annual San Antonio Breast Cancer Symposium. This IHC technique was successful in identifying the activated form of the progesterone receptor via nuclear morphology, which we believe can be done on a routine basis with freshly obtained or formalin-fixed and paraffin-embedded tissue. We are further refining and testing this method on a larger cohort of breast and endometrial cancer samples, with correlation to other standard tumor markers and clinical outcomes. We are also evaluating this diagnostic technique in other malignancies.

In January 2014, we entered into a co-development agreement with Leica Biosystems, or Leica, a global leader in pathology workflow solutions and automation, for the development of a CDx for onapristone. The CDx will be an IHC *in vitro* diagnostic (IVD) test used to detect APR in endometrioid and breast cancer. This CDx test will help to identify patients who are APR positive and therefore more likely to respond to treatment with onapristone. Development of the assay is also ongoing in prostate cancer, as we believe this diagnostic technique will also have potential application in castration-resistant prostate cancer. Under the terms of the co-development agreement, we will sponsor and conduct clinical trials for onapristone. Leica will develop and validate the CDx for APR with responsibility for ensuring the investigational companion diagnostic kit is ready, available and meets FDA and other health authority standards for a planned registration trial of onapristone in endometrioid cancer. The co-development program aims to achieve simultaneous approval and launch of onapristone and the CDx for APR detection.

In February 2014, we entered into an Exclusive Patent License Agreement with the University of Minnesota, pursuant to which we were granted an exclusive, worldwide, royalty-bearing license for the rights to develop and commercialize technology embodied by certain patent applications relating to a gene expression signature derived from archived breast cancer tissue samples. See "—License Agreements and Intellectual Property—University of Minnesota License," below. We plan to develop and commercialize this technology in connection with our CDx development program as a tool to identify progesterone-stimulated pathway activation, which in turn may identify patients who would most likely benefit from treatment with onapristone.

***AR-12***

*Overview*

Pursuant to a license agreement with Ohio State, we have exclusive rights to develop and commercialize AR-12, a potentially first-in-class, orally available cancer treatment that has completed the enrollment of patients in a Phase I clinical study. Preliminary data demonstrates that AR-12 may inhibit multiple different kinase targets. We believe AR-12 may also cause cell death through the induction of stress in the endoplasmic reticulum and work is ongoing to further understand the mechanism of action. In pre-clinical studies, AR-12 has demonstrated activity in a wide range of tumor types and synergistic effects with several widely used anti-cancer agents, enhancing activity or overcoming drug-resistance when used in combination with Avastin® (Genentech), Herceptin® (Genentech), Gleevec® (Novartis), Tarceva® (Genentech) and tamoxifen. *In vitro* screens also suggest that AR-12 may have antimicrobial activity against a broad range of pathogens.

*Mechanism of Action*

AR-12 has been shown in pre-clinical studies to inhibit proteins known as kinases, a novel target in an important cell growth and proliferation pathway, which has been validated by the approval of therapeutics that target proteins both upstream and downstream of PDK-1, a specific kinase. Receptor tyrosine kinases, or RTK, are cell-surface receptors that are involved in cell growth and are upstream of PDK-1. Members of the RTK class are targeted by some of the most successful and widely used targeted oncology agents, including Avastin® (Genentech), Herceptin® (Genentech), Gleevec® (Novartis), Tarceva® (Genentech), Iressa® (AstraZeneca), Nexavar® (Bayer/Onyx) and tamoxifen. Downstream of PDK-1 is the mammalian target of rapamycin, or mTOR protein. The mTOR inhibitors temsirolimus (Torisel®, Wyeth) and everolimus (Afinitor®, Novartis) are FDA approved for the treatment of renal cancer, and additional studies are being conducted with mTOR inhibitors in various clinical trials as anti-cancer agents.

Although FDA-approved drugs that target the Akt pathway have shown efficacy in treating cancer, some tumors either do not respond to these drugs or eventually become resistant to therapy. Scientists hypothesize that a combination of drugs that inhibit different targets in this pathway could provide synergistic or additive benefits to increase efficacy and potentially overcome drug resistance. For this reason, there has been particular interest within the biopharmaceutical industry in developing kinase inhibitors.

AR-12 has also demonstrated an ability to induce the endoplasmic reticulum (ER) stress mediated apoptosis pathway, which contribute to its unique profile *in vitro* and *in vivo*. The ER stress pathway is a cellular mechanism that can either induce cellular protection or apoptosis. AR-12, through the induction of PKR-like Endoplasmic Reticulum Kinase, or PERK, seems to selectively induce the pro-apoptotic response and appears to have a preferential effect on cancer cells. Recent studies suggest that AR-12 down regulates certain molecular protein chaperones including GRP78 (also known as BiP or HSPA5), HSP70 and HSP90. The down regulation of GRP78 may result in the induction of PERK through interactions with other ER stress response elements.

*Potential Advantages of AR-12*

We believe AR-12's unique mechanisms and ability to improve the efficacy of other approved agents may enable it to become a first-in-class agent with broad applications in oncology and significant sales in the market. In preclinical studies, AR-12 has shown efficacy in a wide range of tumor types, including breast, lung, prostate, pancreatic, brain, and hematological cancers, as both a single-agent as well as in combination with leading oncology therapeutics. AR-12 demonstrated synergy or additive benefit or overcame drug-resistance when used in combination with Avastin®, Herceptin®, Gleevec®, Tarceva®, Iressa®, Nexavar® and tamoxifen, all of which are widely-prescribed, FDA-approved oncology therapeutics that, according to Thomson Reuters Pharma, represented approximately $17 billion in sales in 2009. The unique mechanism of action and demonstrated *in vitro* antimicrobial activity may enable AR-12 to be explored as an antimicrobial agent.

*Clinical and Pre-Clinical Development*

We completed study subject enrollment in a multi-site Phase I clinical trial of AR-12 in patients with solid tumors or lymphomas who have progressed despite treatment with other therapies. Subjects in this Phase I study receive an oral daily dose of AR-12. The Phase I study was conducted at three clinical sites, including The Ohio State University (Columbus, Ohio), Scottsdale Healthcare (Phoenix, Arizona), and The Royal Marsden Hospital (London, UK).

The Phase I study of AR-12 was originally designed to be conducted in two parts. The first part was a dose-escalating study, which we refer to as the Escalation Phase, that was primarily designed to evaluate the safety of AR-12 and to identify the maximum tolerated dose, or MTD, or a recommended Phase II dose, or RP2D, for future clinical studies of AR-12. The study is also designed to utilize biomarkers and functional imaging to examine the pharmacodynamic effects of AR-12 in modulating certain targets within the PI3K pathway. Secondary objectives for the Escalation Phase included characterizing the pharmacokinetics of AR-12 (i.e., how AR-12 is absorbed and eliminated in and from the body) and measuring tumor response. We have determined the RP2D and MTD of the current AR-12 formulation. Following the Escalation Phase, we planned to initiate the second part of the study, which we refer to as the Expansion Phase, which would have involved enrolling an expanded cohort of additional patients at the RP2D in multiple tumor types. We will not be moving forward with the Expansion Phase of this study as we plan to conduct

further clinical development of AR-12 with an improved formulation, which has been shown to substantially increase the bioavailability in preclinical models.

We believe that the data generated from the current Phase I study has provided important information to direct future studies, in terms of safety, pharmacokinetics and potential efficacy. We also believe that the biomarkers and pharmacodynamic assays generated in the Phase I study may provide deeper understanding of the molecular actions of AR-12 and validate the preclinical hypothesis about AR-12's activity in a clinical setting. The biomarker selection and evaluation is being led by Johann de Bono, M.D., Ph.D. of The Royal Marsden Hospital in London. The information generated in these studies will also help to guide the potential future development of AR-12.

Additional pre-clinical research of AR-12 conducted by researchers at Ohio State and other institutions indicates that AR-12 may have utility in treating various infectious diseases. We are currently pursuing various opportunities with the potential for securing non-dilutive funding, via government and philanthropic agency grants and contracts, for further research into the possible use of AR-12 as an anti-microbial agent. In April 2015, the EMA granted two orphan drug designations for AR-12 for the treatment of cryptococcosis and tularaemia. Cryptococcosis is an infectious disease of the lungs caused by the fungus *Cryptococcus neoformans* and is one of the most common life-threatening fungal infections in people with AIDS. Tularaemia is an infection which can be spread from animals to humans that is caused by the bacterium *Francisella tularensis* and is a Category A Priority Pathogen on the National Institute of Allergy and Infectious Disease (NIAID) list of Biodefense and Emerging Infectious Diseases.

***AR-42***

*Overview*

Pursuant to a license agreement with The Ohio State University, or Ohio State, we also have exclusive rights to develop and commercialize AR-42, a novel oral cancer therapy currently in early clinical development. AR-42 is a broad spectrum deacetylase inhibitor of both histone and non-histone proteins, which has demonstrated greater potency and activity in solid tumors and hematological malignancies when compared in preclinical studies to vorinostat (also known as "SAHA" or Zolinza®), the first of four marketed compound in the class. AR-42 may possess additional histone-independent mechanisms, which may contribute to its superior profile *in vitro* and *in vivo*. An investigator-initiated dose escalation study with expansion phase of AR-42 in patients with hematological malignancies and solid tumors has been completed at Ohio State. A Phase I investigator-initiated clinical study in combination with decitabine in patients with hematological malignancies has been completed and a Phase 0 investigator-initiated study titled "Exploratory Evaluation of AR-42 Histone Deacetylase Inhibitor in the Treatment of Vestibular Schwannoma and Meningioma" is ongoing.

*Background of HDAC Inhibitors*

Histones are proteins that play an important role in the regulation of genes. Histone modification is a key regulator of gene expression, and improper histone acetylation is among the modifications that are linked to expression of a cancerous phenotype. These changes can lead to improper cell growth resulting from altering the expression of important genes involved in cell cycle progression, proliferation, and survival. Histone deacetylases, or HDACs, are a class of enzymes that participate in this form of regulation and have been linked to both solid and hematologic malignancies and thus represent a target for cancer therapy.

HDAC inhibitors are an emerging class of drug compounds that have demonstrated efficacy primarily in hematological malignancies, also called blood cancers, but are currently being developed in solid tumors as well. It is believed that HDAC inhibitors induce histone hyperacetylation and can cause cell death. The first drug in this class to gain approval is SAHA, which is approved to treat cutaneous T-cell lymphoma, or CTCL, in patients that have failed two previous therapies. Another HDAC inhibitor, romidepsin (Istodax®, Celgene Corporation) is approved to treat CTCL and peripheral T-cell lymphoma. Additionally, belinostat (Beleodaq®, Spectrum) was approved in 2014 for the treatment of patients with relapsed or refractory T-cell lymphoma and panobinostat (Farydak®, Novartis) was approved in 2015 for the treatment of multiple myeloma. The approved compounds and other HDACs are currently in late stage development for both hematological malignancies as well as solid tumors. In preclinical studies, AR-42 has demonstrated activity against a broad spectrum of deacetylase targets and increased potency compared to SAHA.

*Potential Advantages of AR-42*

AR-42 is a broad spectrum inhibitor of histone and non-histone deacetylase targets that we believe may have advantages over currently approved HDAC inhibitors, including SAHA. As a result, many of our preclinical data compare AR-42 to SAHA. In preclinical models, AR-42 has shown to be more potent or effective than SAHA in various cancer types, including chronic lymphocyte leukemia, or CLL, B-cell lymphoma, prostate and ovarian cancers. Further, preclinical studies suggest that AR-42 has anti-cancer activities that are independent of histone acetylation and include Akt dephosphorylation, Bcl-xL and survivin suppression, and Ku70 acetylation, all of which disrupt the growth and proliferation of cancer cells. We believe that this combination of activity and potency could make AR-42 a more effective treatment for hematological malignancies than currently available HDAC inhibitors and a potential treatment of a number of solid tumors. In addition, pre-clinical models have demonstrated anti-tumor activity in tumor types (schwannoma and meningioma) that are associated with the genetic illness neurofibromatosis type 2 (NF2).

In addition to its broad activity against hematological malignancies, pre-clinical data presented at the 2009 American Society of Hematology Annual Meeting showed that AR-42 potently and selectively inhibits leukemic stem cells in acute myeloid leukemia.

*Clinical Development*

We are collaborating with Ohio State, which conducted an investigator-initiated dose escalation study with an expansion phase of AR-42 in patients with advanced or recurrent hematological malignancies and solid tumors for which prior treatments have been ineffective. The primary goal is to evaluate the safety and tolerability of AR-42 given orally three times per week. Secondary endpoints include characterizing AR-42's pharmacokinetics and its pharmacodynamic profile through the measurement of biomarkers and evaluation of clinical response. The recommended dose for further study in patients with hematological malignancies and solid tumors has been declared and the study has been completed. In addition, we also supported an investigator initiated Phase I study of AR-42 at Ohio State in combination with decitabine in patients with hematological malignancies that was initiated in the third quarter of 2013. Decisions regarding the further development of AR-42 will be made upon the completion of these studies and review of the safety/efficacy data.

In February 2012, the FDA granted orphan drug designation for AR-42 for the treatment of meningioma and schwannoma of the central nervous system. Meningioma and schwannoma are rare, benign tumors that can present in different locations within the brain and the spinal cord and may cause substantial morbidity for those affected individuals. The primary treatment option for patients with these tumors is surgical excision. In preclinical studies, AR-42 has demonstrated anti-tumor activity in both meningioma and schwannoma. We believe AR-42 may provide a complement to surgery, particularly in cases where the location of the tumor within the brain or spinal cord precludes surgery. In April 2012, the EMA granted three orphan drug designations for AR-42 for the treatment of meningioma, treatment of schwannoma and treatment of neurofibromatosis-type 2.

**Competition**

We compete primarily in the cancer therapeutic segment of the biopharmaceutical market, which is highly competitive. We face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and selling products designed to address the cancer market. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research capabilities than we do. In addition, many universities and private and public research institutes are active in cancer research. We also compete with commercial biotechnology companies for the rights to product candidates developed by public and private research institutes. Smaller or early-stage companies are also significant competitors, particularly those with collaborative arrangements with large and established companies. In addition to the factors described in this prospectus under the section entitled “Risk Factors,” our ability to compete in the cancer therapeutics market depends on the following factors:

- our ability to develop novel compounds with attractive pharmaceutical properties and to secure and protect intellectual property rights based on our innovations;
- the efficacy, safety and reliability of our drug candidates;
- the speed at which we develop our drug candidates;
- our ability to design and successfully complete appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals;
- our ability to manufacture and sell commercial quantities of future products to the market; and
- acceptance of future products by physicians and other healthcare providers.

***Onapristone***

If approved, onapristone would compete with other classes of oncology drugs referred to as “hormonal” agents (antiestrogens, aromatase inhibitors, megestrol acetate, androgen receptor inhibitors) used in the treatment of endometrial, prostate and breast cancers. Antiestrogens, aromatase inhibitors, and megestrol acetate have been used for a number of decades and the medical community is aware and accepting of their safety and efficacy profile. Many of these agents are off patent and thus available at a low cost. In addition, combination chemotherapy is routinely used after patients with breast and endometrial cancer have failed standard hormonal treatments, and thus onapristone may be positioned as an agent which delays the need for chemotherapy. Additionally, drugs that inhibit the androgen receptor (Zytiga® (abiraterone acetate) marketed by Janssen, Xtandi® (enzalutamide) marketed by Astellas) have been approved for the treatment of metastatic castration resistant prostate cancer and are projected to generate over $2 billion in combined revenue in 2015.

Although previous formulations of onapristone have a known risk for elevated liver function tests, we believe that our proprietary formulation and onapristone's historical therapeutic profile will allow it to compete successfully in the crowded space of breast cancer treatments and, potentially, as an effective treatment for women with endometrial carcinoma and men with castration resistant prostate cancer.

***AR-12***

AR-12 is believed to target multiple kinases. Kinase inhibition has been of great interest to the pharmaceutical industry, particularly compounds that target PI3K. The approaches for targeting PI3K are general inhibition or the specific inhibition of the alpha, beta, gamma, or delta subunit of this kinase. Some of these molecules also combine PI3K inhibition with activity against the mammalian target of rapamycin ("mTOR"), a target that is believed to also play a role in the PI3K/Akt pathway. Other approaches to this pathway include targeting Akt directly. Additionally, companies such as Wyeth, Vernalis, GlaxoSmithKline, and Novartis have published data on their preclinical discovery programs to target PDK-1.

Compounds that inhibit PI3K have been the foundation of several recent licensing, acquisition, and financing activities. Despite the great deal of activity in the space, we believe that AR-12 can differentiate itself and become an important agent in the treatment of cancer. In multiple preclinical studies, AR-12 has demonstrated the ability to inhibit multiple kinases as well as induce ER stress, a combination that could provide a unique therapeutic profile and differentiate AR-12 from other molecules being developed to inhibit the PI3K/Akt pathway.

***AR-42***

If approved, AR-42 would compete with other HDAC inhibitors. HDAC inhibitors have displayed efficacy in a broad range of settings as single agents and in combination with other therapeutics. The first HDAC inhibitor to obtain approval is vorinostat ("SAHA," or Zolinza®), which is approved for the treatment of recurrent cutaneous T-cell lymphoma ("CTCL"). Other FDA approved HDAC inhibitors include, romidepsin, (Istodax®, Celgene Corporation) which has been approved for the treatment of patients with peripheral T-cell lymphoma, belinostat (Beleodaq®, Spectrum) for the treatment of patients with relapsed or refractory T-cell lymphoma and panobinostat (Farydak®, Novartis) for the treatment of patients with multiple myeloma. These and other HDAC inhibitors are in Phase II and Phase III clinical trials, primarily in hematological malignancies, but also in solid tumors as both single agents and in combination with other oncology therapies.

We believe that AR-42 has a therapeutic profile that will allow it to compete successfully in the crowded class of what are broadly known as HDAC inhibitors. AR-42 is a pan-DAC inhibitor that has demonstrated preclinical activity that compares favorably with SAHA, as well as potentially differentiating activity and the ability to target cancer stem cells. Additionally, based on AR-42's preclinical toxicology package and dosing schedule, we believe that there is a relatively low risk of cardiac toxicity or fatigue. We also believe that AR-42's potential to selectively target leukemic stem cells in AML may sufficiently differentiate AR-42 from other agents in the class to become an important member of the emerging class of deacetylase inhibitors.

**License Agreements and Intellectual Property**

***General***

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and abroad. However, even patent protection may not always afford us with complete protection against competitors who seek to circumvent our patents. If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish. See "Risk Factors – Risks Related to Our Intellectual Property."

We will continue to depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

***Onapristone License Agreement***

Our rights to onapristone are governed by a license agreement with Invivis dated February 13, 2012. Under this agreement, we hold an exclusive, royalty-bearing license for the rights to commercialize onapristone for all therapeutic uses. The license agreement provides us with worldwide rights to onapristone with the exception of

France, although under the license agreement we have an option to acquire French commercial rights from Invivis by providing notice to Invivis and making a cash payment.

The onapristone license agreement with Invivis provides us with exclusive, worldwide rights to a U.S. patent application that relates to assays for predictive biomarkers for anti-progestin efficacy. We intend to expand our patent portfolio by filing additional patent applications covering the use and manufacture of onapristone and/or a companion diagnostic product. If the pending patent application issues, the issued patent would be scheduled to expire in 2031.

We made a one-time cash payment of $500,000 to Invivis upon execution of the license agreement on February 13, 2012. Additionally, Invivis will receive performance-based cash payments of up to an aggregate of $15.1 million upon successful completion of clinical and regulatory milestones relating to onapristone, which milestones include the marketing approval of onapristone in multiple indications in the United States or the European Union as well as Japan. The first milestone was due upon the dosing of the first patient in a pharmacokinetic study and was achieved during August 2013 and we made a $150,000 payment to Invivis during October 2013. We made our next milestone payment of $100,000 to Invivis upon the dosing of the first subject in the first Company-sponsored Phase I clinical trial of onapristone in January 2014. A milestone payment of $350,000 for the enrollment of the first patient in a Phase II clinical trial sponsored by Arno was paid in July 2015. In addition, we will pay Invivis low single digit sales royalties based on net sales of onapristone by us or any of our sublicensees. Pursuant to a separate services agreement which expired in April 2014, Invivis provided us with certain clinical development support services, which included the assignment of up to two full-time employees to perform such services, in exchange for a monthly cash payment of approximately $70,833. Effective April 1, 2014, we renewed the services agreement for a period of one year for a monthly cash payment of $50,000 and certain other performance based milestones. The services agreement was not renewed upon its expiration on April 1, 2015.

Under the license agreement with Invivis, we also agreed to indemnify and hold Invivis and its affiliates harmless from any and all claims arising out of or in connection with the production, manufacture, sale, use, lease, consumption or advertisement of onapristone, provided, however, that we shall have no obligation to indemnify Invivis for claims that (a) any patent rights infringe third party intellectual property, (b) arise out of the gross negligence or willful misconduct of Invivis, or (c) result from a breach of any representation, warranty confidentiality obligation of Invivis under the license agreement. The license agreement will terminate upon the later of (i) the last to expire valid claim contained in the patent rights, and (ii) February 13, 2032. In general, Invivis may terminate the license agreement at any time upon a material breach by us to the extent we fail to cure any such breach within 90 days after receiving notice of such breach or in the event we file for bankruptcy. We may terminate the agreement for any reason upon 90 days’ prior written notice.

***University of Minnesota License***

In February 2014, we entered into an Exclusive Patent License Agreement with the Regents of the University of Minnesota, or UM, pursuant to which we were granted an exclusive, worldwide, royalty-bearing license for the rights to develop and commercialize technology embodied by certain patent applications relating to a gene expression signature derived from archived breast cancer tissue samples. We plan to develop and commercialize this technology as part of our companion diagnostic development program as a tool to identify progesterone-stimulated pathway activation, which in turn may identify patients who would be more likely to benefit from treatment with onapristone.

The license agreement requires us to use commercially reasonable efforts to commercialize the licensed technology as soon as practicable, and includes several performance milestones relating to the development and commercialization of the technology to be achieved by us at specified dates. Under the terms of the agreement, we made a small one-time cash payment and reimbursed UM for past patent expenses it has incurred. The agreement also provides that we will pay royalties to UM on net sales of "Licensed Products" (as defined in the agreement) at a rate in the low-single digits, which royalty obligation terminates on a licensed product-by-licensed product and country-by-country basis upon the first date when there is no longer a valid claim under a licensed patent or patent application covering such licensed product in the country where the licensed product is made or sold.

The term of the license agreement continues until the last date on which there is any active licensed patent or pending patent application. UM may terminate the agreement earlier upon a breach by us of one or more of our obligations that remains uncured for a period specified in the agreement. UM may also terminate the agreement if we voluntarily file for bankruptcy or similar proceeding, or if a petition for an involuntary bankruptcy proceeding is filed and is not released for 60 days. The agreement may be immediately terminated upon notice to us if we commence or maintain a proceeding in which we assert that the licensed patents are invalid or unenforceable. We may terminate the agreement at any time and for any reason upon 90 days' written notice.

The license agreement further provides that we will indemnify and hold UM and its affiliates harmless from any and all suits, actions, claims, liabilities, demands, damages, losses or expenses relating to our exercise of our rights under the agreement, including our right to commercialize the licensed technology. UM is required to indemnify us with respect to claims relating to or resulting from its breach of the agreement.

***AR-12 and AR-42 License Agreements***

Our rights to AR-12 and AR-42 are governed by separate license agreements with The Ohio State University Research Foundation, or Ohio State, entered into in January 2008. Pursuant to each of these agreements, we have exclusive,

worldwide, royalty-bearing licenses for the rights to commercialize technologies embodied by certain issued patents, patent applications, know-how and improvements relating to AR-12 and AR-42 for all therapeutic uses.

Under our license agreement for AR-12, we have exclusive, worldwide rights to seven issued U.S. patent and three pending U.S. patent applications that relate to AR-12, AR-12 analogs, and particular uses of AR-12 according to our business plan. The issued patents include composition of matter claims. The issued patents are currently scheduled to expire in 2024. If the pending patent applications issue, the latest of the issued patent or patents would be scheduled to expire in 2034. In 2014, we filed a provisional patent application directed to methods of using AR-12 that, if issued, would expire in 2035. In addition, Arno has exclusive rights to a pending US and international patent application directed to AR-12 formulations which, if issued, would expire in 2034.

Under our license agreement for AR-42, we have exclusive, worldwide rights to one issued and two pending U.S. patent applications that relate to AR-42 and particular uses of AR-42 according to our business plan. If one of the pending patent applications issues, the issued patent or patents would be scheduled to expire in 2024. If the other pending patent application issues, it would be scheduled to expire in 2034.

In 2008, pursuant to our license agreements for AR-12 and AR-42, we made one-time cash payments to Ohio State in the aggregate amount of $450,000 and reimbursed it for past patent expenses. Additionally, we are required to make performance-based cash payments upon successful completion of clinical and regulatory milestones relating to AR-12 and AR-42 in the U.S., Europe and Japan. The license agreements for AR-12 and AR-42 provide for aggregate potential milestone payments of up to $6.1 million for AR-12, of which $5.0 million is due only after marketing approval in the United States, Europe and Japan, and $5.1 million for AR-42, of which $4.0 million is due only after marketing approval in the United States, Europe and Japan. In September 2009, we paid Ohio State a milestone payment upon the commencement of the Phase I clinical study of AR-12. Pursuant to the license agreements for AR-12 and AR-42, we must pay Ohio State royalties on net sales of licensed products at rates in the low-single digits. To the extent we enter into a sublicensing agreement relating to either or both of AR-12 or AR-42, we will be required to pay Ohio State a portion of all non-royalty income received from such sublicensee.

The license agreements with Ohio State further provide that we will indemnify Ohio State from any and all claims arising out of the death of or injury to any person or persons or out of any damage to property, or resulting from the production, manufacture, sale, use, lease, consumption or advertisement of either AR-12 or AR-42, except to the extent that any such claim arises out of the gross negligence or willful misconduct of Ohio State. The license agreements for AR-12 and AR-42, respectively, expire on the later of (i) the expiration of the last valid claim contained in any licensed patent and (ii) 20 years after the effective date of the license. Ohio State will generally be able to terminate either license upon our breach of the terms of the license to the extent we fail to cure any such breach within 90 days after receiving notice of such breach or our bankruptcy. We may terminate either license upon 90 days prior written notice.

**Government Regulation and Product Approval**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the testing (pre-clinical and clinical), manufacturing, labeling, storage, recordkeeping, advertising, promotion, import, export, marketing and distribution, among other things, of drugs and drug product candidates. If we do not comply with applicable requirements, we may be fined, the regulatory agencies may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. We and our manufacturers may also be subject to regulations under other United States federal, state, and local laws.

***United States Government Regulation***

In the United States, the FDA regulates drugs under the Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following (although the FDA is given wide discretion to impose different or more stringent requirements on a case-by-case basis):

- completion of extensive pre-clinical laboratory tests, pre-clinical animal studies and formulation studies, all performed in accordance with the FDA's good laboratory practice regulations and other regulations;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- performance of multiple adequate and well-controlled clinical trials meeting FDA requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission of a new drug application, or NDA, to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product candidate is produced, and potentially other involved facilities as well, to assess compliance with current good manufacturing practice, or cGMP, regulations and other applicable regulations; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all. Risks to us related to these regulations are described above under the caption entitled "Risk Factors – Risks Relating to the Clinical Testing, Regulatory Approval, Manufacturing and Commercialization of Our Product Candidates."

Pre-clinical tests may include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity and other effects in animals. The results of pre-clinical tests, together with manufacturing information and analytical data, among other information, are submitted to the FDA as part of an IND application. Subject to certain exceptions, an IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, issues a clinical hold to delay a proposed clinical investigation due to concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND, or those of our collaboration partners, may not result in the FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. The FDA must also approve changes to an existing IND. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

*Clinical Trials*

For purposes of NDA submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap (although additional or different trials may be required by the FDA as well):

- *Phase I clinical trials are* initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, in patients, such as patients with cancer. In some cases, particularly in cancer trials, a sponsor may decide to conduct what is referred to as a "Phase Ib" evaluation, which is a second safety-focused Phase I clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently FDA-approved drugs or in a particular patient population.

- *Phase II clinical trials are* generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II clinical trial that could, if accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.

- *Phase III clinical trials are* commonly referred to as randomized and/or pivotal trials. When Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

In some cases, the FDA may condition continued approval of an NDA on the sponsor's agreement to conduct additional clinical trials with due diligence. In other cases, the sponsor and the FDA may agree that additional safety and/or efficacy data should be provided; however, continued approval of the NDA may not always depend on timely submission of such information. Such post-approval studies are typically referred to as Phase IV studies.

*New Drug Application*

The results of drug candidate development, pre-clinical testing and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, and the payment of a user fee, are submitted to the FDA as part of an NDA. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once an NDA is accepted for filing, the FDA begins an in-depth review of the application.

During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA may refuse to approve an NDA and issue a "not approvable" letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical or other data, including one or more additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaboration partners interpret data. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. The FDA may withdraw drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the FDA-approved indications and in accordance with the FDA-approved label. Further, if there are any modifications to the drug, including changes in indications, other labeling changes, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

*The Hatch-Waxman Act*

Under the Hatch-Waxman Act, newly-approved drugs and new conditions of use may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active entity. The Hatch-Waxman Act prohibits the submission of an abbreviated NDA, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, submission of a Section 505(b)(2) NDA or an ANDA for a generic version of a previously-approved drug containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act does not prevent the submission or approval of another "full" 505(b)(1) NDA; however, the applicant would be required to conduct its own pre-clinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Some of our product candidates may qualify for Hatch-Waxman non-patent marketing exclusivity.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the drug for which the applicant submitted the NDA or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our product candidates.

Finally, the Hatch-Waxman Act amended the patent laws so that certain patents related to products regulated by the FDA are eligible for a patent term extension if patent life was lost during a period when the product was undergoing regulatory review, and if certain criteria are met. We intend to seek patent term extensions, provided our patents and products, if they are approved, meet applicable eligibility requirements.

*Pediatric Studies and Exclusivity*

The FDA provides an additional six months of non-patent marketing exclusivity and patent protection for any such protections listed in the Orange Book for new or marketed drugs if a sponsor conducts specific pediatric studies at the written request of the FDA. The Pediatric Research Equity Act of 2003, or PREA, authorizes the FDA to require pediatric studies for drugs to ensure the drugs' safety and efficacy in children. PREA requires that certain new NDAs or NDA supplements contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from PREA. PREA pediatric assessments may qualify for pediatric exclusivity. Unless otherwise required by regulation, PREA does not apply to any drug for an indication with orphan designation.

*Orphan Drug Designation and Exclusivity*

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process, but does qualify the sponsor of the drug for various incentives such as tax credits for qualified clinical testing and waiver of the required application fee for use of the drug in the orphan designation. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is

entitled to seven years of orphan drug exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity (superior efficacy, safety, or a major contribution to patient care). Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication. In February 2012, AR-42 received orphan-drug designation from the FDA for the treatment of meningioma and schwannoma of the central nervous system, which are benign tumors that can present in different locations within the brain and the spinal cord and may cause substantial morbidity for those affected individuals. Where appropriate, we will also seek US orphan drug designation for our other product candidates, including potentially for certain uses of AR-12.

Under European Union medicines laws, the criteria for designating a product as an “orphan medicine” are similar but somewhat different from those in the United States. A drug is designated as an orphan drug if the sponsor can establish that the drug is intended for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union or that is unlikely to be profitable, and if there is no approved satisfactory treatment or if the drug would be a significant benefit to those persons with the condition. Orphan medicines are entitled to ten years of marketing exclusivity, except under certain limited circumstances comparable to United States law. During this period of marketing exclusivity, no “similar” product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits. On March 8, 2012 the European Medicines Agency, Committee on Orphan Medicinal Products (COMP) issued a positive opinion on the application for orphan designation of AR-42 for treatment of neurofibromatosis-type 2 disease complex.

*Fast Track Designation*

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If the FDA grants fast track designation, it may initiate review of sections of an NDA before the application is complete. This so-called "rolling review" is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant has paid applicable user fees. The FDA's review clock for both a standard and priority NDA for a fast track product does not begin until the complete application is submitted. Additionally, fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by emerging data, or if the designated drug development program is no longer being pursued.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

In some cases, a fast track designated drug candidate may also qualify for one or more of the following programs:

- *Priority Review.* As explained above, a drug candidate may be eligible for a six-month priority review. The FDA assigns priority review status to an application if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track drug would ordinarily meet the FDA's criteria for priority review, but may also be assigned a standard review. We do not know whether any of our drug candidates will be assigned priority review status or, if priority review status is assigned, whether that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately approve the drug.

- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival or irreversible morbidity. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies with due diligence, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, may cause the FDA to seek to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

When appropriate, we and/or our collaboration partners intend to seek fast track designation, accelerated approval or priority review for our drug candidates. We cannot predict whether any of our drug candidates will obtain fast track, accelerated approval, or priority review designation, or the ultimate impact, if any, of these expedited review mechanisms on the timing or likelihood of the FDA approval of any of our drug candidates.

Satisfaction of the FDA regulations and approval requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with some of the drug candidates we are developing, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for changes in dosage form or new indications for our drug candidates on a timely basis, or at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug candidates would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

*Special Protocol Assessment*

The FDCA directs the FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment, or SPA. While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has the latitude to change its assessment if certain exceptions apply. Exceptions include identification of a substantial scientific issue essential to safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

*Other Regulatory Requirements*

Any drugs manufactured or distributed by us or our collaboration partners pursuant to future FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, sales or use, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning and/or untitled letters, corrective advertising and potential civil and criminal penalties.

*Foreign Regulation*

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future products.

**Manufacturing**

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to accelerate development of our product candidates rather than diverting resources to establish our own manufacturing facilities. We meet our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. We rely on individual proposals and purchase orders to meet our needs and typically rely on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). We do not have any long-term agreements or commitments for these services. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of our product candidates, some of which are available from only a single supplier.

Should any of our product candidates obtain marketing approval, we anticipate establishing relationships with third-party manufacturers and other service providers in connection with the commercial production of our products. We have some flexibility in securing other manufacturers to produce our product candidates; however, our alternatives may be limited due to proprietary technologies or methods used in the manufacture of some of our product candidates.

**Research and Development Expenses**

We spent approximately $8.7 million in fiscal year 2015 and $14.8 million in fiscal year 2014 on research and development activities. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs.

**Employees**

As of the date of this prospectus, we have four full-time employees, none of whom are covered by a collective bargaining agreement. We believe our relations with our employees are satisfactory.

We retain several consultants who serve in various operational and administrative capacities, and we utilize clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, and manufacturing. We may hire additional research and development staff, as required, to support our product development.

**Legal Proceedings**

We are not involved in any pending legal proceedings.

**Description of Property**

Our principal offices are located at 200 Route 31 North, Suite 104, Flemington, New Jersey 08822, where we occupy approximately 4,168 square feet of office space pursuant to the terms of an amended lease agreement dated June 17, 2014. The lease commencement date was November 17, 2011, with lease payments beginning in February 2012. The

lease expiration date, as amended, is January 31, 2018. We provided a cash security deposit of $10,455, or two months' base rent. We are also responsible for payment of our share of common area maintenance costs and taxes.

## MANAGEMENT AND BOARD OF DIRECTORS

### Directors and Executive Officers

The following table lists our executive officers, directors and key employees and their respective ages and positions as of the date of this prospectus:

| Name | Age | Positions |
|---|---|---|
| Arie S. Belldegrun, M.D. | 66 | Chairman of the Board |
| Alexander Zukiwski, M.D. | 58 | Chief Executive Officer, Chief Medical Officer and Director |
| David M. Tanen | 44 | Secretary and Director |
| Stefan Proniuk, Ph.D. | 45 | Chief Development Officer |
| William F. Hamilton, Ph.D. | 76 | Director |
| Tomer Kariv | 54 | Director |
| Jay Moorin | 64 | Director |
| Yacov Reizman | 64 | Director |
| Steven B. Ruchefsky | 54 | Director |

***Arie S. Belldegrun, M.D., FACS.*** Dr. Belldegrun has served as our Chairman of the Board of Directors since March 2008. Since June 2009, Dr. Belldegrun has been founder and Executive Chairman of Kite Pharma, Inc., a publicly-held biotechnology company based in Los Angeles, CA. In March 2014, he was also appointed to serve as Kite Pharma's President and Chief Executive Officer, an interim position he held since December 2013. Dr. Belldegrun also currently serves as Chairman of TheraCoat Ltd., a pharmaceutical company, a position he has held since December 2012, as Chairman and Partner of Two River Consulting LLC, a consulting firm, since June 2009, and as a Director of Teva Pharmaceutical Industries Ltd., a pharmaceutical company, a position he has held since March 2013. He also served as a Director of Nile Therapeutics, Inc., a biotechnology company, from September 2009 to November 2013 and as a Director of SonaCare Medical, LLC, a healthcare company, from October 2009 to October 2014. In 1996, he founded Agensys, Inc., a biotechnology company, and served as its founding Chairman from 1996 to 2001, and continued to serve on the board until 2007 when it was acquired by Astellas Pharma Inc. Dr. Belldegrun was also the Founding Vice-Chairman of the board of directors and Chairman of the scientific advisory board of Cougar Biotechnology, Inc., a biotechnology company, from 2003 to 2009 when it was acquired by Johnson & Johnson. He is certified by the American Board of Urology, and is a Fellow of the American College of Surgeons and the American Association of Genitourinary Surgeons. Dr. Belldegrun is Professor of Urology, holds the Roy and Carol Doumani Chair in Urologic Oncology, and Director of the Institute of Urologic Oncology at the David Geffen School of Medicine at the University of California, Los Angeles, or UCLA. Prior to joining UCLA in October of 1988, he was at the NCI/NIH as a research Fellow in surgical oncology and immunotherapy from July 1985 to August 1988 under Dr. Steven A. Rosenberg. Dr. Belldegrun completed his M.D. at the Hebrew University Hadassah Medical School in Jerusalem, his post graduate studies in Immunology at the Weizmann Institute of Science and his residency in Urologic Surgery at Harvard Medical School.

***Alexander Zukiwski, M.D.*** joined Arno as Vice President and Chief Medical Officer in June 2011, was appointed to serve as Arno's Chief Executive Officer in July 2014, and was added to the Board of Directors in December 2014. Dr. Zukiwski has more than 15 years of experience in global oncology drug development and was most recently Executive Vice President, Clinical Research, and Chief Medical Officer at MedImmune, Inc. where he served until March 2011, leading the organization that was responsible for developing and implementing MedImmune's clinical research, medical affairs and safety strategies. From 2002 until he joined MedImmune in 2007, Dr. Zukiwski held medical affairs and clinical development positions of increasing responsibility at Johnson & Johnson Pharmaceutical Research & Development, LLC ("JJPRD"), Centocor and Ortho Biotech, all Johnson & Johnson companies, including serving as therapeutic area head for oncology and acting head of oncology research and development. As Vice President, Head of Clinical Oncology, he was responsible for strategic oversight and portfolio management of therapeutic oncology, hematology and supportive care clinical development programs for JJPRD and Centocor's oncology development group. Before joining Johnson & Johnson, Dr. Zukiwski held clinical oncology positions at Hoffmann-LaRoche, Glaxo Wellcome and Rhone- Poulenc Rorer. Dr. Zukiwski received a bachelor's degree in pharmacy from the University of Alberta and a Doctor of Medicine degree from the University of Calgary. He conducted his post-graduate training at St. Thomas Hospital Medical Center in Akron, Ohio and the University of Texas, M.D. Anderson Cancer Center.

***David M. Tanen*** is a co-founder of Arno and has served as a director and its secretary since its inception. Mr. Tanen also served as Arno's President from June 2009 until April 2011. Mr. Tanen also serves as an Officer and Director of Riverbank Capital Securities, Inc., a broker dealer registered with FINRA ("Riverbank"), which engages in private placement activities for public and private companies, primarily in the life science sector, and which performed placement agent services for Arno in 2008 and 2010. Mr. Tanen also serves as an officer of the managing member of Two River Consulting, LLC, which provides management, operational and other services for Arno. See "Transactions with Related Persons, Promoters and Certain Control Persons." Prior to founding Two River, from October 1996 to September 2004, Mr. Tanen was a Director of Paramount BioCapital Investments, LLC, a biotechnology focused venture capital company. Mr. Tanen also served as a member of the General Partner of the Orion Biomedical Fund, LP. Mr. Tanen received his B.A. from The George Washington University and his J.D. from Fordham University School of Law.

***Stefan Proniuk, Ph.D.*** has over 17 years of experience in pharmaceutical product development. Since joining Arno in 2008, Dr. Proniuk has assumed roles of increasing responsibility. In his current position, he is responsible for the preclinical, chemical and pharmaceutical development of Arno's portfolio. Prior to joining Arno, Dr. Proniuk was at Neurocrine Biosciences where he was responsible for overseeing development programs from Phase I to III. His group was also responsible for the transition of discovery leads into development candidates of new chemical entities (NCEs). Prior to his work at Neurocrine, Dr. Proniuk worked at Cima Labs on the development and scale-up of fast dissolving tablet formulations. Throughout his career he has worked on multiple regulatory submissions and marketed products. Dr. Proniuk holds a Ph.D. degree in Pharmaceutical Sciences from the University of Arizona, an MBA with emphasis in Entrepreneurship from San Diego State University and a Diplom (FH) in Chemical Engineering from the University of Applied Sciences Isny, Germany.

***William F. Hamilton, Ph.D.*** was appointed to Arno's board of directors in October 2008. Dr. Hamilton has served on the University of Pennsylvania faculty since 1967, and is the Landau Professor of Management and Technology, and Director of the Jerome Fisher Program in Management and Technology at The Wharton School and the School of Engineering and Applied Science. Dr. Hamilton received his B.S. and M.S. in chemical engineering and his MBA from the University of Pennsylvania, and his Ph.D. in applied economics from the London School of Economics.

***Tomer Kariv,*** a director of Arno since September 2010, is the co-founder and Chief Executive Officer of Pontifax, a group of Israeli based life sciences venture funds focusing on investments in development stage bio-pharmaceutical and med-tech technologies. Mr. Kariv serves as an active board member of many of the funds' portfolio companies, assuming a special responsibility for strategic planning. Among others, Mr. Kariv serves as the Chairman of Check-Cap Ltd and as the Chairman of Macrocure Ltd. During the 10 years prior to establishing Pontifax in 2004, Mr. Kariv played a key role in investing, managing and nurturing technology driven companies and startups and has held senior management positions at top Israeli financial institutions. Mr. Kariv practiced law with Sullivan & Cromwell, a leading corporate law firm in New York, and holds a B.A. in Economics from Harvard University and a J.D. from Harvard Law School.

***Jay Moorin*** was appointed to Arno's board of directors in January 2016. Since 1998, Mr. Moorin has served as a founding general partner of ProQuest Investments, a healthcare venture capital firm. From 1991 to 1998, Mr. Moorin served as president and chief executive officer of Magainin Pharmaceuticals Inc., a publicly-traded biopharmaceutical company, and also served as chairman of its Board of Directors from 1996 to 1998. He is also currently Chairman of the Board of Eagle Pharmaceuticals, Inc., a publicly-traded specialty pharmaceutical company, serves on the Board of Directors of a private radiation therapy company and serves as a trustee of the Equinox Funds Trust. Previously, Mr. Moorin served as managing director of healthcare banking at Bear Stearns & Co. Inc. and vice president of marketing and business development at a division of the ER Squibb Pharmaceutical Company. Mr. Moorin held the position of adjunct senior fellow of the Leonard Davis Institute of Health Economics at the University of Pennsylvania from 1997 to 2012. Previously, Mr. Moorin served on the board of directors of numerous public and private healthcare companies. Mr. Moorin holds a B.A. in economics from the University of Michigan.

***Yacov Reizman***, a director of Arno since September 2010, has been the Chairman and Chief Executive Officer of FCC Ltd., a private investment company that he founded in 1987. Over the past decade FCC has invested directly in over 50 publicly traded and privately held companies in a diverse range of industries including: infrastructure; shipping; healthcare; and financial services. FCC also specializes in corporate finance and structured investments. Mr. Reizman was also co-founder and co-CEO of Azimuth Ltd., which traded on the TASE. Previously Mr. Reizman served in the Israeli Air Force (IAF) as a fighter pilot (Major) and led large-scale high-tech projects for the IAF, including joint projects with Israeli and U.S. defense industries. Mr. Reizman holds a B.A. in economics and in psychology from Tel Aviv University.

***Steven Ruchefsky***, a director of Arno since September 2010, has been the President of Commercial Street Capital LLC, a private investment company, since January 2010. Since September 2001, Mr. Ruchefsky has been working as a private investment manager for S. Donald Sussman, the founder and Chief Executive Officer of a multi-billion dollar hedge fund. Mr. Ruchefsky currently sits on the boards of directors of several private and public companies, including Kite Pharma, Inc., a Los Angeles-based biotechnology company (since February 2011), and Itamar Medical Ltd., an Israeli-based medical technology company. Mr. Ruchefsky was previously a partner at Morrison Cohen, New York City. Mr. Ruchefsky is a graduate of The George Washington University Law School.

**Experience, Qualifications, Attributes and Skills of Directors**

We look to our directors to lead us through our continued growth as a clinical-stage public biopharmaceutical company. We believe our directors bring their leadership experience from a variety of life science companies and professional backgrounds which we require to continue to grow and bring value to our stockholders. Messrs. Kariv, Moorin, Reizman, Ruchefsky and Tanen have venture capital or investment banking backgrounds and offer expertise in financing and growing small companies, particularly small biopharmaceutical and life science companies. Each of Drs. Belldegrun and Hamilton and Messrs. Moorin and Tanen have significant experience with early stage private and public companies and bring depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Dr. Belldegrun's medical background and experience serving as an investigator in clinical trials of oncology drug candidates allows him to contribute significant medical and scientific expertise. Dr. Zukiwski's extensive drug development experience and his current position as our Chief Executive Officer and Chief Medical Officer allow him to provide a unique insight into our development and growth. As a result of his academic experience and his prior service on the audit committees of several publicly-traded life sciences companies, Dr. Hamilton also brings extensive finance, accounting and risk management knowledge to us.

**Independence of the Board of Directors**

In determining whether the members of our board of directors and its committees are independent, we have elected to use the definition of "independence" set forth in the listing standards of the NASDAQ Stock Market. After considering all relevant relationships and transactions, our board of directors, in consultation with legal counsel, has determined that Messrs. Kariv, Moorin, Reizman, Ruchefsky and Dr. Hamilton are "independent" within the meaning of the applicable listing standard of the NASDAQ Stock Market. Drs. Belldegrun and Zukiwski and Mr. Tanen are not independent, as defined by applicable NASDAQ listing standards.

**Executive Compensation**

The following table sets forth all of the compensation for the 2015 and 2014 fiscal years awarded to, earned by or paid to (i) our principal executive officer during the fiscal year ended December 31, 2015; (ii) the only other individual that served as an executive officer at the conclusion of the fiscal year ended December 31, 2015 and who received in excess of $100,000 in total compensation during such fiscal year; and (iii) one additional individual who received in excess of $100,000 in total compensation during the fiscal year ended December 31, 2015 but was not serving as an executive officer at the end of such fiscal year. We refer to these individuals as our named executive officers.

Summary Compensation Table

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Options Awards ($) (1) | All Other Compensation ($) (2) | Total ($) |
|---|---|---|---|---|---|---|
| Alexander A. Zukiwski, M.D. (3) | 2015 | 435,000 | 108,750 | - | 12,000 | 555,750 |
| Chief Executive Officer and Chief Medical Officer | 2014 | 424,320 | 190,944 | 1,551,440 | 12,000 | 2,178,704 |
| Stefan Proniuk, Ph.D. | 2015 | 256,250 | 42,075 | - | - | 298,325 |
| Chief Development Officer | 2014 | 230,200 | 76,378 | 374,886 | - | 681,464 |
| Lawrence A. Kenyon (4) | 2015 | 230,208 | - | - | 8,500 | 238,708 |
| Former Chief Operating Officer and Chief Financial Officer | 2014 | 234,455 | 77,324 | 375,100 | 10,250 | 697,129 |

(1) Except as otherwise noted, amounts reflect the grant date fair value of stock awards and option awards granted under the Company's 2005 Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 *"Compensation- Stock Compensations"*.

(2) All Other Compensation amounts represent automobile allowance.

(3) Dr. Zukiwski was appointed to the additional role of Chief Executive Officer in July 2014.

(4) Mr. Kenyon was hired to serve as our Chief Financial Officer in February 2014 and was subsequently appointed to the additional role of Chief Operating Officer in July 2014. Mr. Kenyon resigned his employment with Arno effective as of September 15, 2015.

**Employment Agreements, Termination of Employment and Change-in-Control Arrangements**

***Alexander Zukiwski, M.D.***

***Chief Executive Officer and Chief Medical Officer***

Dr. Zukiwski's employment with us is governed by an employment agreement dated June 22, 2011. The term of the agreement expires on June 22, 2015, subject to automatic renewal for successive one-year periods until either party provides the other party with at least 90 days' prior written notice of nonrenewal. Pursuant to the employment agreement, Dr. Zukiwski was entitled to an initial annualized base salary of $375,000, which was subsequently increased to $394,000 for 2012, to $408,000 for 2013, to $424,320 for 2014 and to $435,000 for 2015. The employment agreement further provides that, subject to the successful achievement of specific performance objectives to be established by the Board, Dr. Zukiwski will be eligible to receive an annual performance bonus of up to 50% of his annualized base salary. For 2014 our Board awarded Dr. Zukiwski a performance bonus of $190,944, representing 90% of his target bonus. For 2015 our Board awarded Dr. Zukiwski a performance bonus of $108,750, representing 50% of his target bonus. Pursuant to his employment agreement, we also agreed to reimburse Dr. Zukiwski in an amount up to $200,000 for expenses incurred in connection with the relocation of Dr. Zukiwski's primary residence to the northern New Jersey area, which amounts are subject to repayment as described in the employment agreement in the event of Dr. Zukiwski's voluntary termination of his employment (other than for "Good Reason," as defined in the employment agreement) or Arno's termination of his employment for "Cause" (as defined in the employment agreement).

Pursuant to the employment agreement, on the date of the agreement, Dr. Zukiwski was granted 10-year options to purchase a total of 218,750 shares of our common stock at an exercise price equal to $8.00 per share. Options relating to 50% of such shares are designated as "Employment Options" and options relating to the remaining 50% of the shares are designated as "Performance Options." The right to purchase 25% of the shares subject to the Employment Options vested immediately and the remaining shares subject to the Employment Options vested and became exercisable in 24 equal monthly installments thereafter. The right to purchase the shares subject to the Performance Options was to vest and become exercisable, if at all, with respect to one-third of the shares in each calendar year, or a pro-rata portion thereof for a period less than a full year, subject to the successful achievement of specific performance objectives to be established by the Board. On January 17, 2012, the Board determined that, for the pro-rated period ended December 31, 2011, Dr. Zukiwski's Performance Options would vest in the maximum potential amount of 19,278 shares. On January 14, 2013, the Board determined that, for the calendar year ended December 31, 2012, Dr. Zukiwski's Performance Options would vest in the maximum potential amount of 36,458 shares. The right to purchase the remaining shares subject to the Performance Options lapsed unvested.

On January 14, 2013, Dr. Zukiwski was granted 10-year options to purchase a total of 73,125 shares of our common stock at an exercise price equal to $2.40 per share. Options relating to 50% of such shares are designated as "Employment Options" and options relating to the remaining 50% of the shares are designated as "Performance Options." The right to purchase one-third of the shares subject to the Employment Options vested immediately and the remaining shares subject to the Employment Options vested and became exercisable in 24 equal monthly installments commencing January 31, 2013. The right to purchase one-third of the shares subject to the Performance Options vested immediately and the right to purchase the remaining shares lapsed unvested.

Also on January 14, 2013, the Board determined that the exercise price applicable to all stock options previously granted to Dr. Zukiwski would be reduced from $8.00 to $2.40, the conversion price of the Debentures issued in our 2012 offering of debentures and warrants, which the Board determined represented the fair market value of our common stock at such time.

On October 7, 2013, our board of directors authorized a grant of a 10-year stock option under the 2005 Plan to Dr. Zukiwski to purchase a number of shares of our common stock equal to 4.5% of the total number of shares issuable by us upon the conversion of our outstanding Debentures issued 2012. Accordingly, after all of the Debentures were converted on October 29, 2013, our board granted to Dr. Zukiwski a 10-year stock option to purchase 316,389 shares, which option vests in 36 equal monthly installments commencing on the first month anniversary of the date of grant and continuing each month thereafter until fully vested, provided that such vesting shall accelerate upon a "change of control" of the Company, as such term is defined under the 2005 Plan (but excluding any transaction conducted primarily for purposes of raising capital). The exercise price of such option is $2.40 per share.

On January 24, 2014, Dr. Zukiwski was granted 10-year options to purchase a total of 711,301 shares of our common stock at an exercise price equal to $2.90 per share. The right to purchase one-third of the shares subject to such grant vested on the first anniversary of the grant date and the remaining shares will thereafter vest and become exercisable in 24 equal monthly installments.

On April 7, 2016, Dr. Zukiwski was granted 10-year options to purchase a total of 2,303,567 shares of our common stock at an exercise price equal to $0.37 per share. Of such amount, options relating to 1,196,070 shares are designated as "Employment Options" and options relating to the remaining 1,107,497 shares are designated as "Warrant Contingent Options." For both the Employment Options and the Warrant Contingent Options, the right to purchase one-third of the shares subject to such options will vest and become exercisable on the first anniversary of the grant date and the remaining shares will thereafter vest and become exercisable in 24 equal monthly installments; provided, however, that notwithstanding the foregoing vesting schedule, the Warrant Contingent Options will only be exercisable to the extent the warrants to purchase shares of our common stock outstanding as of April 7, 2016 (excluding the 2013 Series C Warrants) are exercised, calculated on a pro-rata basis. To the extent such warrants expire unexercised, the Warrant Contingent Options will terminate as to the number of option shares allocable to the unexercised warrants.

The employment agreement provides that if Arno terminates Dr. Zukiwski without "Cause," or if he resigns for "Good Reason" (each as defined in agreement), then he shall be entitled to: (i) any earned but unpaid performance bonus; (ii) continued payment of his then current annualized base salary for a period of 12 months; and (iii) the acceleration of the vesting of the Employment Options such that all unvested Employment Options shall be deemed vested as of the termination date. In addition to the foregoing, in the event that Dr. Zukiwski's employment is terminated 60 days prior to or within 12 months following a "Change in Control" (as defined in the employment agreement), Dr. Zukiwski shall also be entitled to the immediate vesting of all unvested Performance Options.

***Stefan Proniuk, Ph.D.***

***Chief Development Officer***

Dr. Proniuk's employment with us is governed by a letter agreement dated January 31, 2008, as amended on August 22, 2010. The letter agreement initially provided for Dr. Proniuk's employment as our Director of Product Development on an at-will basis. Dr. Proniuk was subsequently promoted to Vice President of Product Development in January 2012 and as our Chief Development Officer in October 2014. Dr. Proniuk's agreement provided for an annual base salary of $150,000, subject to increases; his base salary was increased to $215,000 effective January 1, 2013, $223,600 effective January 1, 2014 and to $255,000 effective October 1, 2014. In addition, the letter agreement provides that Dr. Proniuk is eligible to receive an annual performance bonus of up to 15% of his base salary upon the successful completion of annual corporate and individual milestones, which target percentage was subsequently increased to 25% on January 1, 2010, to 33% on January 1, 2012, and, solely with respect to the 2013 fiscal year, was increased to 50%. Since January 1, 2014, Dr. Proniuk's target percentage has been 33%. For 2014, our Board awarded Dr. Proniuk a performance bonus of $76,378, representing 100% of his target bonus. For 2015, our Board awarded Dr. Proniuk a performance bonus of $42,075, representing 50% of his target bonus.

Pursuant to the letter agreement, on the date of the agreement, Dr. Proniuk was granted 10-year options to purchase 9,968 shares of our common stock at an exercise price of $19.36, with one-fourth vesting after one year and the remainder vesting in 36 equal monthly installments thereafter. In addition, on June 20, 2011, Dr. Proniuk was granted 10-year options to purchase a total of 31,250 shares of our common stock at an exercise price equal to $8.00 per share. Options relating to 55% of such shares were designated as “Employment Options” and options relating to the remaining 45% of the shares were designated as “Performance Options.” The right to purchase 3,125 of the shares subject to the Employment Options vested immediately and, of the remaining shares, 25% vested on the first anniversary of the grant date, with the remainder vesting in 24 equal monthly installments thereafter. The right to purchase the shares subject to the Performance Options was to vest and become exercisable, if at all, with respect to one-third of the shares in each calendar year, or a pro-rata portion thereof for a period less than a full year, subject to the successful achievement of specific performance objectives to be established by the Board. On January 17, 2012, the Board determined that, for the pro-rated period ended December 31, 2011, Proniuk’s Performance Options would vest in the maximum potential amount of 2,504 shares. On January 14, 2013, the Board determined that, for the calendar year ended December 31, 2012, Dr. Proniuk’s Performance Options would vest in the maximum potential amount of 4,687 shares. The right to purchase the remaining shares subject to the Performance Options lapsed unvested.

On September 19, 2011, in consideration for cancelling the 10-year options to purchase 9,968 shares of our common stock that were issued to Dr. Proniuk on January 31, 2008, Dr. Proniuk was granted 10-year options to purchase 10,000 shares of our common stock at an exercise price of $8.00, with one-half immediately vested and the remainder vesting in 24 equal monthly installments commencing October 19, 2011.

On January 14, 2013, Dr. Proniuk was granted 10-year options to purchase a total of 13,750 shares of our common stock at an exercise price equal to $2.40 per share. Options relating to 50% of such shares are designated as “Employment Options” and options relating to the remaining 50% of the shares are designated as “Performance Options.” The right to purchase one-third of the shares subject to the Employment Options vested immediately and the remaining shares subject to the Employment Options will vested and became exercisable in 24 equal monthly installments commencing January 31, 2013. The right to purchase one-third of the shares subject to the Performance Options vested immediately and the right to purchase the remaining shares lapsed unvested.

Also on January 14, 2013, the Board determined that the exercise price applicable to all stock options previously granted to Dr. Proniuk would be reduced from $8.00 to $2.40, the conversion price of the Debentures issued in our 2012 offering of debentures and warrants, which the Board determined represented the fair market value of our common stock at such time.

On October 7, 2013, our board of directors authorized a grant of a 10-year stock option under the 2005 Plan to Dr. Proniuk to purchase a number of shares of our common stock equal to 0.65% of the total number of shares issuable by us upon the conversion of our outstanding Debentures issued 2012. Accordingly, after all of the Debentures were converted on October 29, 2013, our board granted to Dr. Proniuk a 10-year stock option to purchase 45,701 shares, which option vests in 36 equal monthly installments commencing on the first month anniversary of the date of grant

and continuing each month thereafter until fully vested, provided that such vesting shall accelerate upon a “change of control” of the Company, as such term is defined under the 2005 Plan (but excluding any transaction conducted primarily for purposes of raising capital). The exercise price of such option is $2.40 per share.

On January 24, 2014, Dr. Proniuk was granted 10-year options to purchase a total of 171,877 shares of our common stock at an exercise price equal to $2.90 per share. The right to purchase one-third of the shares subject to such grant vested on the first anniversary of the grant date and the remaining shares will thereafter vest and become exercisable in 24 equal monthly installments.

On April 7, 2016, Proniuk was granted 10-year options to purchase a total of 1,068,294 shares of our common stock at an exercise price equal to $0.37 per share. Of such amount, options relating to 554,685 shares are designated as “Employment Options” and options relating to the remaining 513,609 shares are designated as “Warrant Contingent Options.” For both the Employment Options and the Warrant Contingent Options, the right to purchase one-third of the shares subject to such options will vest and become exercisable on the first anniversary of the grant date and the remaining shares will thereafter vest and become exercisable in 24 equal monthly installments; provided, however, that notwithstanding the foregoing vesting schedule, the Warrant Contingent Options will only be exercisable to the extent the warrants to purchase shares of our common stock outstanding as of April 7, 2016 (excluding the 2013 Series C Warrants) are exercised, calculated on a pro-rata basis. To the extent such warrants expire unexercised, the Warrant Contingent Options will terminate as to the number of option shares allocable to the unexercised warrants.

**Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information concerning stock options held by the named executive officers at December 31, 2015:

| Name | Number of Securities Underlying Unexercised Options Exercisable | Number of Securities Underlying Unexercised Options Unexercisable | Option Exercise Price ($) | Option Expiration Date | |
|---|---|---|---|---|---|
| Alexander A. Zukiwski, M.D. | 109,375 | - | 2.40 | 6/22/2021 | (1) |
| | 55,736 | - | 2.40 | 6/22/2021 | (2) |
| | 36,562 | - | 2.40 | 1/14/2023 | (3) |
| | 12,187 | - | 2.40 | 1/14/2023 | (4) |
| | 219,714 | 96,975 | 2.40 | 11/4/2023 | (5) |
| | 422,334 | 288,967 | 2.90 | 1/24/2024 | (6) |
| Stefan Proniuk, Ph. D. | 17,187 | - | 2.40 | 6/22/2021 | (7) |
| | 7,191 | - | 2.40 | 6/22/2021 | (8) |
| | 10,000 | - | 2.40 | 9/19/2021 | (9) |

| | | | | | |
|---|---|---|---|---|---|
| | 6,875 | - | 2.40 | 1/14/2023 | (10) |
| | 2,291 | - | 2.40 | 1/14/2023 | (11) |
| | 31,736 | 13,965 | 2.40 | 11/4/2023 | (12) |
| | 102,051 | 69,826 | 2.90 | 1/24/2024 | (13) |
| Lawrence A. Kenyon | 97,757 | - | 2.23 | 3/31/2016 | (14) |

(1) Options granted June 22, 2011 relating to an aggregate of 109,375 shares, of which 25% vested on the first anniversary of the grant date and the remainder vested in 24 equal monthly installments thereafter.

(2) Options granted June 22, 2011 relating to an aggregate of 109,375 shares and vesting up to one-third in each calendar year, or a pro-rata portion thereof for a period less than a full year, at the discretion of the board of directors.

(3) Options granted January 14, 2013 relating to an aggregate of 36,562 shares, of which one-third vested immediately and the remainder vest in 24 equal monthly installments thereafter, commencing January 31, 2013.

(4) Options granted January 14, 2013 relating to an aggregate of 36,562 shares, of which one-third vested immediately and up to one-half of the remainder vest annually based on the achievement of performance milestones as determined by the board of directors.

(5) Options granted November 4, 2013 relating to an aggregate of 316,389 shares and vesting in 36 equal monthly installments commencing December 4, 2013.

(6) Options granted January 24, 2014 relating to an aggregate of 711,301 shares, of which 25% vested on the first anniversary of the grant date and the remainder vest in 24 equal monthly installments thereafter.

(7) Options granted June 22, 2011 relating to an aggregate of 17,187 shares, of which 3,125 shares vested immediately and, of the remaining shares, 25% vested on the first anniversary of the grant date, with the remainder vesting in 24 equal monthly installments thereafter.

(8) Options granted June 22, 2011 relating to an aggregate of 14,062 shares and vesting up to one-third in each calendar year, or a pro-rata portion thereof for a period less than a full year, at the discretion of the board of directors.

(9) Options granted Sept 19, 2011 relating to an aggregate of 10,000 shares, of which 50% vested immediately and the remainder vested in 24 equal monthly installments commencing October 19, 2011.

(10) Options granted January 14, 2013 relating to an aggregate of 6,875 shares, of which one-third vested immediately and the remainder vested in 24 equal monthly installments thereafter, commencing January 31, 2013.

(11) Options granted January 14, 2013 relating to an aggregate of 6,875 shares, of which one-third vested immediately and up to one-half of the remainder vest annually based on the achievement of performance

milestones as determined by the board of directors.

(12) Options granted November 4, 2013 relating to an aggregate of 45,701 shares and vesting in 36 equal monthly installments commencing December 4, 2013.

(13) Options granted January 24, 2014 relating to an aggregate of 171,877 shares, of which 25% vested on the first anniversary of the grant date and the remainder vest in 24 equal monthly installments thereafter.

(14) Options granted February 24, 2014 relating to an aggregate of 223,445 shares, of which 25% vested on the first anniversary of the grant date and the remainder were scheduled to vest in 24 equal monthly installments thereafter. However, Mr. Kenyon resigned as Arno's Chief Operating Officer and Chief Financial Officer effective as of September 15, 2015, and all future vesting of Mr. Kenyon's options ceased as of such date. Mr. Kenyon's options remained exercisable, to the extent vested as of his resignation, until their termination on March 31, 2016.

**Director Compensation**

Prior to October 7, 2013, our non-employee directors were entitled to receive the following in consideration for their service on the Board: (1) an annual retainer of $25,000; (2) a stock option grant of 3,750 shares of the Company's common stock upon their initial appointment or election to the Board; and (3) an annual stock option grant of 1,250 shares of the Company's common stock. In addition, any non-employee director designated as chairman of the Board was entitled to an annual retainer of $10,000, the chair of the Board's audit committee was entitled to an additional annual retainer of $8,000, and the chairs of the Board's compensation and nominating & corporate governance committees were entitled to annual retainers of $4,000. In addition, as our chairman, Dr. Belldegrun received an annual retainer equal to $150,000. Stock options awarded to our non-employee directors have a 10-year term, vest in three equal annual installments commencing on the first anniversary of the grant date, and have an exercise price equal to the fair market value of the Company's common stock on the grant date. The Board deferred granting its annual stock options for 2015.

Effective October 7, 2013, our board of directors adopted a new non-employee director compensation plan which provides the following compensation to our non-employee directors for their service on our Board: (1) an annual cash retainer of $50,000; (2) a 10-year stock option under the 2005 Plan to purchase a number of shares of our common stock equal to 0.10% of our then outstanding shares of common stock upon his or her initial appointment or election to the Board, which vests in 36 equal monthly installments commencing on the first month anniversary of the grant date; and (3) an annual 10-year stock option under the 2005 Plan to purchase a number of shares of our common stock equal to 0.05% of our then outstanding shares of common stock, which option vests in its entirety on the first anniversary of the grant date. In addition, any non-employee director designated as chairman of the Board is entitled to an annual retainer of $150,000, the chairs of the Board's audit and finance committees are entitled to additional annual retainers of $10,000, and the chairs of the Board's compensation and nominating & corporate governance committees are entitled to additional annual retainers of $5,000. The Chairman of the Board shall also be entitled to receive a stock option to purchase a number of shares of our common stock equal to 0.20% of our then outstanding shares of common stock upon his or her initial appointment or election to the Board and an annual stock option to purchase a number of shares equal to 0.10% of our then outstanding shares of common stock. Stock options awarded to our non-employee directors have a 10-year term, have an exercise price equal to the fair market value of our common stock on the grant date, and vest in their entirety upon a "change of control" of the Company, as such term is defined in the plan pursuant to which such options are granted.

In addition to the stock options issuable pursuant to the non-employee director compensation plan adopted on October 7, 2013, on November 4, 2013, the Board approved grants under the 2005 Plan of 10-year stock options to Dr. Belldegrun and Mr. Ruchefsky to purchase 3,422,300 and 136,896 shares of our common stock, respectively, which amounts represent 5.0% and 0.20%, respectively, of our fully-diluted outstanding shares of common stock on such grant date. Such additional stock option grants are subject to the same terms and conditions as the initial option grants issuable to our non-employee directors, as described above. Further, our board of directors authorized the grants of additional 10-year stock options to Mr. Ruchefsky, subject to his continued service, to purchase a number of shares of our common stock equal to 0.20% and 0.10%, respectively, of the then fully-diluted outstanding shares of our common stock. Each of the additional stock options would be granted to Mr. Ruchefsky on November 4, 2014 and November 4, 2015, respectively, and shall vest and become exercisable in 36 equal monthly installments commencing on the first month anniversary of the applicable grant date, shall be exercisable at the then fair market value of the common stock (as determined in accordance with our stock option pricing policy in effect on the date of grant), and shall vest and become exercisable upon a change of control, as described in the 2005 Plan. In accordance with such arrangement, on November 4, 2014, Mr. Ruchefsky was granted an option to purchase 136,784 shares of our common stock at an exercise price of $0.85 per share, and on November 4, 2015, Mr. Ruchefsky was granted an option to purchase 48,399 shares of our common stock at an exercise price of $0.36 per share.

The following table sets forth the compensation paid to our non-employee directors for their service in 2015.

| Name | **Fees Earned or Paid in Cash** ($) | Option Awards ($)(1)(2) | Total ($) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Arie S. Belldegrun, M.D. | 150,000 | - | 150,000 |
| William F. Hamilton, Ph. D. | 62,843 | - | 62,843 |
| Tomer Kariv | 54,000 | - | 54,000 |
| Yacov Reizman | 54,500 | - | 54,500 |
| Steven B. Ruchefsky | 65,000 | 12,187 | 77,187 |
| David M. Tanen | 50,500 | - | 50,500 |

(1) Except as otherwise noted, amounts reflect the grant date fair value of stock awards and option awards granted under the Company's 2005 Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 *"Compensation- Stock Compensations"*.

(2) As of December 31, 2015, the aggregate number of option awards outstanding for each director was as follows; Arie S. Belldegrun, M.D., options to purchase 3,692,666 shares; William F. Hamilton, Ph. D., options to purchase 107,672 shares; Tomer Kariv, options to purchase 106,422 shares; Yacov Reizman, options to purchase 106,422 shares; Steven B. Ruchefsky, options to purchase 428,501 shares; and David M. Tanen, options to purchase 105,172 shares.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table summarizes certain information regarding the beneficial ownership (as such term is defined in Rule 13d-3 under the Exchange Act) of our common stock as of April 18, 2016 by: (i) each of our current directors, (ii) each of our "named executive officers," as defined above under "Executive Compensation," (iii) all of our current directors and executive officers as a group, and (iv) each person known by us to be the beneficial owner of more than 5% of our common stock. Except as indicated in the footnotes below, the security and stockholders listed below possess sole voting and investment power with respect to their shares. Except as otherwise indicated, the address of each of our executive officers and directors identified below is 200 Route 31 North, Suite 104, Flemington, New Jersey 08822.

| Name of Beneficial Owner | No. Shares of Common Stock Beneficially Owned (1) | Percent of Class (1) |
|---|---|---|
| Arie S. Belldegrun, M.D. (2) | 8,567,556 | 18.3 |
| Alexander Zukiwski (3) | 1,543,315 | 3.6 |
| Lawrence A. Kenyon (4) | - | - |
| David M. Tanen (5) | 662,854 | 1.6 |
| Stefan Proniuk, Ph.D. (6) | 246,359 | * |
| William F. Hamilton, Ph.D. (7) | 173,955 | * |
| Tomer Kariv (8) | 4,872,169 | 11.2 |
| Yacov Reizman (9) | 149,971 | * |
| Steven B. Ruchefsky (10) | 7,600,982 | 17.0 |
| Jay Moorin (11) | 655,170 | 1.6 |
| All current executive officers and directors as a group (9 persons) | 24,472,331 | 45.3 |
| | | |
| Pontifax (8) | 4,872,169 | 11.2 |
| Commercial Street Capital, LLC (10) | 7,600,982 | 17.0 |
| Bonderman Family LP (12)(13) | 5,729,305 | 9.9 |
| Green Fields Offshore, Inc. (14) | 3,506,448 | 8.0 |
| OPKO Health, Inc. (15) | 3,105,249 | 7.2 |
| Perceptive Life Sciences Master Fund Ltd. (12)(16) | 12,415,496 | 9.9 |
| Quantum Partners LP (12)(17) | 14,885,565 | 9.9 |
| Sabby Management, LLC (12)(18) | 4,434,692 | 9.9 |
| Auriga Investors (19) | 2,236,485 | 5.3 |
| Ronald I. Dozoretz (20) | 3,039,469 | 7.2 |

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* represents less than 1%.

(1) Based upon 41,562,613 issued and outstanding shares of our common stock as of April 18, 2016. Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Beneficial ownership includes: (i) 3,115 shares of our common stock and 3,227,861 shares issuable upon the exercise of stock options held by Dr. Belldegrun; (ii) 379,294 shares of our common stock, 428,920 shares issuable upon the exercise of 2012 Series A Warrants, and 350,467 shares issuable upon the exercise of 2013 Series D Warrants held by Arie and Rebecka Belldegrun as Trustees of the Belldegrun Family Trust dated February 18, 1994; (iii) 1,548,543 shares of our common stock and 245,096 shares issuable upon the exercise of 2012 Series A Warrants held by the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan; (iv) 858,095 shares of our common stock and 194,702 shares issuable upon the exercise of 2013 Series D Warrants held by Leumi Overseas Trust Corporation Limited ("Leumi") as Trustee of the BTL Trust; (v) 254,887 shares of our common stock, 367,646 shares issuable upon the exercise of 2012 Series A Warrants, and 194,702 shares issuable upon the exercise of 2013 Series D Warrants held by Leumi as Trustee of the Tampere Trust; and (vi) 174,644 shares of our common stock, 183,822 shares issuable upon the exercise of 2012 Series A Warrants, and 155,762 shares issuable upon the exercise of 2013 Series D Warrants held by MDRB Partnership, L.P. ("MDRB"). Dr. Belldegrun is a beneficiary of each of the BTL Trust and the Tampere Trust and is the managing partner of MDRB. Dr. Belldegrun holds voting and/or dispositive power over the shares held by MDRB and the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan. Richard J. Guillaume and John Le M Germain, directors of Leumi, hold voting and/or dispositive power over the shares held by Leumi as trustee of each of the BTL Trust and the Tampere Trust.

(3) Beneficial ownership includes 261,832 shares of our common stock, 183,822 shares issuable upon the exercise of 2012 Series A Warrants, 77,880 shares issuable upon the exercise of 2013 Series D Warrants, and 1,019,781 shares issuable upon the exercise of stock options.

(4) Mr. Kenyon resigned as Arno's Chief Operating Officer and Chief Financial Officer effective as of September 15, 2015.

(5) Beneficial ownership includes: (i) 171,712 shares of our common stock and 110,436 shares issuable upon the exercise of stock options held by Mr. Tanen; (ii) 362,015 shares of our common stock held by the David M. Tanen Revocable Trust (the "Tanen Trust"); and (iii) 18,691 shares held by Mr. Tanen's minor children. Gregory Kiernan, the trustee of the Tanen Trust, holds voting and/or dispositive power over the shares held by the Tanen Trust.

(6) Beneficial ownership includes 10,047 shares of our common stock, 24,508 shares issuable upon the exercise of 2012 Series A Warrants, and 211,804 shares issuable upon the exercise of stock options.

(7) Beneficial ownership includes 22,079 shares of our common stock, 38,940 shares issuable upon the exercise of 2013 Series D Warrants, and 112,936 shares issuable upon the exercise of stock options.

(8) The business address for Pontifax is 14 Shenkar Street, Herzeliya 46140 Israel. Beneficial ownership includes: (i) 111,686 shares issuable upon the exercise of stock options held by Mr. Kariv; and (ii) 2,756,183 shares of our common stock and 2,004,300 shares issuable upon the exercise of warrants held by affiliates of Pontifax, of which Mr. Kariv is chief executive officer. Mr. Kariv and Ran Nussbaum hold voting and/or dispositive power over the shares held by Pontifax.

(9) Beneficial ownership includes: (i) 111,686 shares issuable upon the exercise of stock options held by Mr. Reizman; and (ii) 38,285 shares of our common stock held by FCC Ltd., of which Mr. Reizman is chairman and chief executive officer.

(10) The business address for Commercial Street Capital LLC is 800 Westchester Avenue, Rye Brook, NY 10573. Beneficial ownership includes: (i) 311,170 shares issuable upon the exercise of stock options held by Mr. Ruchefsky; and (ii) 4,472,905 shares of our common stock and 2,816,907 shares issuable upon the exercise of warrants held by Commercial Street Capital, LLC, of which Mr. Ruchefsky is president. Mr. Ruchefsky holds voting and/or dispositive power over the shares held by Commercial Street Capital, LLC.

(11) Beneficial ownership includes 642,858 shares of our common stock and 12,312 shares issuable upon the exercise of stock options.

(12) Notwithstanding the number of shares of our common stock shown as beneficially owned by the security holder in the table above, the warrants held by the security holder provide that the security holder may not exercise such warrants to the extent that the security holder would beneficially own in excess of 9.99% of our outstanding common stock immediately after giving effect to such exercise.

(13) The business address for Bonderman Family LP is 301 Commerce Street, Suite 3000, Fort Worth, TX 76102. Beneficial ownership includes 2,336,448 shares issuable upon the exercise of warrants. Leonard Potter holds voting and/or dispositive power over the shares held by Bonderman Family LP.

(14) The business address for Green Fields Offshore, Inc. is Four Seasons Residences, Spring 19D, Jl. Setiabudi Tengah, Jakarta, 12910 Indonesia. Beneficial ownership includes 2,405,968 shares issuable upon the exercise of warrants. Anton Linderum holds voting and/or dispositive power over the shares held by Green Fields Offshore, Inc.

(15) The business address for OPKO Health, Inc. is 4400 Biscayne Blvd., Miami, FL 33137. Beneficial ownership includes 1,557,631 shares issuable upon the exercise of warrants. Steven Rubin holds voting and/or dispositive power over the shares held by OPKO Health, Inc.

(16) The business address for Perceptive Life Sciences Master Fund Ltd. is 499 Park Avenue, 25th Floor New York, NY 10022. Beneficial ownership includes 9,145,061 shares issuable upon the exercise of warrants. Joseph Edelman holds voting and/or dispositive power over the shares held by Perceptive Life Sciences Master Fund Ltd.

(17) The business address for Quantum Partners LP is 888 Seventh Avenue, New York, NY 10106. Beneficial ownership includes 10,812,150 shares issuable upon the exercise of warrants. Soros Fund Management LLC ("SFM") serves as principal investment manager to Quantum Partners LP. As such, SFM has been granted investment discretion over portfolio investments, including the shares reported in the table above, held for the account of Quantum Partners LP. George Soros serves as Chairman of SFM and Robert Soros serves as President

and Deputy Chairman of SFM.

(18) The business address for Sabby Management, LLC is 10 Mountainview Road, Suite 205, Upper Saddle River, NJ 07458. Beneficial ownership includes: (i) with respect to Sabby Healthcare Master Fund, Ltd., 1,204,900 shares of our common stock, 1,531,861 shares issuable upon the exercise of 2012 Series A Warrants, and 584,112 shares issuable upon the exercise of 2013 Series D Warrants; and (ii) with respect to Sabby Volatility Warrant Master Fund, Ltd., 919,117 shares issuable upon the exercise of 2012 Series A Warrants, and 194,702 shares issuable upon the exercise of 2013 Series D Warrants. Sabby Management, LLC serves as the investment manager of each of Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (collectively, the "Sabby Funds"). Hal Mintz is the manager of Sabby Management, LLC. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the shares held by the Sabby Funds except to the extent of its pecuniary interest therein.

(19) The business address for Auriga Investors is 5-Rue Jean Monnet, L-2180 Luxembourg. Beneficial ownership includes: (i) 25,000 shares of our common stock and 46,728 shares issuable upon the exercise of warrants held by Auriga Global Investors SV, SA; (ii) 811,222 shares of our common stock and 919,117 shares issuable upon the exercise of warrants held by A.I. Montserrat Global Fund; and (iii) 434,418 shares of our common stock held by Montserrat Healthcare Fund. Dr. Raj Mehra holds voting and/or dispositive power over the shares held by Auriga Global Investors SV, SA, A.I. Montserrat Global Fund, and Montserrat Healthcare Fund.

(20) Mr. Dozoretz's business address is 240 Corporate Blvd., Suite 110, Norfolk, VA 23502. Beneficial ownership includes: (i) 2,142,857 shares of our common stock held by Mr. Dozoretz, and (ii) 312,500 shares of our common stock and 584,112 shares issuable upon the exercise of warrants held by FHC Stock Holdings, LLC. Mr. Dozoretz holds voting and/or dispositive power over the shares held by FHC Stock Holdings, LLC.

## TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

Dr. Belldegrun and Mr. Tanen, each a current director and substantial stockholder of Arno, and Mr. Joshua A. Kazam, a director until September 2010, control Two River Consulting, LLC, or TRC. From 2010 to 2013, certain employees of TRC, including Mr. Tanen, our former President, and Mr. Scott L. Navins, our former Treasurer, performed substantial services for us, including without limitation operational, managerial, financial, clinical and regulatory activities for which we paid TRC a monthly consulting fee of $55,000 pursuant to a services agreement. While the term of the services agreement expired on April 1, 2011, we continued to utilize the services of TRC on an as needed basis until December 2013. Other than the payments to TRC, we did not pay any salary or other compensation to Messrs. Tanen and Navins for their services to us through December 2013. From January 1, 2014 to March 15, 2014, we directly employed Mr. Navins as our VP of Finance and Treasurer, for which he was paid a salary.

## WHERE YOU CAN FIND MORE INFORMATION

Federal securities laws require us to file information with the SEC concerning our business and operations. Accordingly, we file annual, quarterly, and special reports, proxy statements and other information with the SEC. You can inspect and copy this information at the Public Reference Facility maintained by the SEC at Judiciary Plaza, 100 F Street, N.E., Washington, D.C. 20549. You can receive additional information about the operation of the SEC's Public Reference Facilities by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding companies that, like us, file information electronically with the SEC.

## VALIDITY OF COMMON STOCK

Legal matters in connection with the validity of the shares offered by this prospectus will be passed upon by Fredrikson & Byron, P.A., Minneapolis, Minnesota.

## EXPERTS

The financial statements as of December 31, 2015 and 2014, and for the years then ended, included in this prospectus, have been so included in reliance on the report of Crowe Horwath LLP, independent registered public accounting firm, given on the authority of said firm as experts in accounting and auditing.

**TRANSFER AGENT**

The transfer agent for our common stock is American Stock Transfer & Trust Company, and its address is 40 Wall Street, New York, New York, 10005.

**DISCLOSURE OF COMMISSION POSITION ON**

**INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

ARNO THERAPEUTICS, INC.

**INDEX TO FINANCIAL STATEMENTS**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and stockholders

Arno Therapeutics, Inc.

Flemington, New Jersey

We have audited the accompanying balance sheets of Arno Therapeutics, Inc. as of December 31, 2015 and 2014, and the related statements of operations, stockholders' (deficit) equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the years then ended are in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses from operations and negative operating cash flows that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ Crowe Horwath LLP

New York, New York

March 30, 2016

ARNO THERAPEUTICS, INC.

BALANCE SHEETS

| | December 31, 2015 | December 31, 2014 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | $ 66,988 | $ 7,948,436 |
| Prepaid expenses and other current assets | 260,694 | 258,046 |
| Total current assets | 327,682 | 8,206,482 |
| Property and equipment, net | 23,103 | 30,730 |
| Security deposit | 10,455 | 10,455 |
| Total assets | $ 361,240 | $ 8,247,667 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current liabilities | | |
| Accounts payable | $ 1,010,215 | $ 742,448 |
| Accrued expenses and other current liabilities | 1,124,690 | 1,410,293 |
| Convertible notes, net of financing costs of $10,091 | 2,089,909 | - |
| Capital lease obligation- short term | 3,853 | 3,322 |
| Deferred rent | 1,910 | 1,048 |
| Total current liabilities | 4,230,577 | 2,157,111 |
| Capital lease obligation- long term | 4,070 | 7,923 |
| Derivative liabilities | 4,750,687 | 6,671,524 |
| Total liabilities | 8,985,334 | 8,836,558 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' DEFICIT | | |
| Preferred stock, $0.0001 par value, 35,000,000 shares authorized, none issued and outstanding | - | - |
| Common stock, $0.0001 par value, 500,000,000 shares authorized, 20,408,616 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively | 5,469 | 5,469 |
| Additional paid-in capital | 84,665,390 | 81,192,630 |
| Accumulated deficit | (93,294,953) | (81,786,990) |
| Total stockholders' deficit | (8,624,094) | (588,891) |

| | | |
|---|---|---|
| Total liabilities and stockholders' deficit | $ 361,240 | $ 8,247,667 |

See accompanying notes to financial statements

ARNO THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Operating expenses: | | |
| Research and development | $8,653,008 | $14,840,302 |
| General and administrative | 4,758,803 | 6,653,024 |
| Total operating expenses | 13,411,811 | 21,493,326 |
| Loss from operations | (13,411,811) | (21,493,326) |
| Other income/(expense): | | |
| Interest income | 7,658 | 41,954 |
| Interest expense | (28,403) | (143) |
| Other income, net | 1,924,593 | 29,222,282 |
| Total other income/(expense) | 1,903,848 | 29,264,093 |
| Net income/(loss) | $(11,507,963) | $7,770,767 |
| Net income/(loss) per share - basic | $(0.56) | $0.38 |
| Weighted-average shares outstanding- basic | 20,408,616 | 20,381,554 |
| Net income/(loss) per share - diluted | $(0.56) | $0.31 |
| Weighted-average shares outstanding- diluted | 20,408,616 | 24,809,995 |

See accompanying notes to financial statements

ARNO THERAPEUTICS, INC.

STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY

| | PREFERRED STOCK SHARES | PREFERRED STOCK AMOUNT | COMMON STOCK SHARES | COMMON STOCK AMOUNT | ADDITIONAL PAID-IN CAPITAL | ACCUMULATED DEFICIT | TOTAL STOCKHOLDERS' DEFICIT |
|---|---|---|---|---|---|---|---|
| Balance at January 1, 2014 | - | - | 20,370,331 | 5,465 | 76,668,966 | (89,557,757) | (12,883,326) |
| Net income | - | - | - | - | - | 7,770,767 | 7,770,767 |
| Stock based compensation for services | - | - | - | - | 4,523,668 | - | 4,523,668 |
| Issuance of Common Stock | - | - | 38,285 | 4 | (4) | | 0 |
| Balance at December 31, 2014 | - | - | 20,408,616 | $ 5,469 | $ 81,192,630 | $ (81,786,990) | $ (588,891) |
| Net loss | - | - | - | - | - | (11,507,963) | (11,507,963) |
| Stock based compensation for services | - | - | - | - | 3,472,760 | - | 3,472,760 |
| Balance at December 31, 2015 | - | - | 20,408,616 | $ 5,469 | $ 84,665,390 | $ (93,294,953) | $ (8,624,094) |

See accompanying notes to financial statements

ARNO THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Cash flows from operating activities: | | |
| Net income/(loss) | $(11,507,963) | $7,770,767 |
| Adjustment to reconcile net income/(loss) to net cash and cash equivalents used in operating activities: | | |
| Depreciation and amortization | 7,627 | 12,586 |
| Stock-based compensation | 3,472,760 | 4,523,668 |
| Change in fair value of derivative liability | (1,920,837) | (29,193,357) |
| Amortization of financing costs | 2,437 | |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (2,648) | (171,780) |
| Accounts payable | 267,767 | (2,199,550) |
| Accrued expenses | (285,603) | 485,038 |
| Deferred rent | 862 | (6,749) |
| Due to related party | - | (26,039) |
| Net cash used in operating activities | (9,965,598) | (18,805,416) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | - | (20,096) |
| Net cash used in investing activities | - | (20,096) |
| Cash flows from financing activities: | | |
| Payment of capital lease obligation | (3,322) | (255) |
| Convertible notes financing issuance costs | (12,528) | - |
| Proceeds from issuance of convertible notes payable | 2,100,000 | - |
| Net cash provided by financing activities | 2,084,150 | (255) |
| Net decrease in cash and cash equivalents | (7,881,448) | (18,825,767) |
| Cash and cash equivalents at beginning of period | 7,948,436 | 26,774,203 |
| Cash and cash equivalents at end of period | $66,988 | $7,948,436 |
| Supplemental schedule of cash flows information: | | |
| Cash paid for interest | $1,139 | $143 |
| Supplemental schedule of non-cash investing and financing activities: | | |

| | | |
|---|---|---|
| Acquisition of equipment pursuant to capital leases | $- | $11,500 |

See accompanying notes to financial statements

**ARNO THERAPEUTICS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

Years ended December 31, 2015 and 2014

## 1. DESCRIPTION OF BUSINESS

Arno Therapeutics, Inc. (“Arno” or the “Company”) is developing innovative drug candidates intended to treat patients with cancer and other life threatening diseases. The Company was incorporated in Delaware in March 2000, at which time its name was Laurier International, Inc. (“Laurier”). Pursuant to an Agreement and Plan of Merger dated March 6, 2008 (as amended, the “Merger Agreement”), by and among the Company, Arno Therapeutics, Inc., a Delaware corporation formed on August 1, 2005 (“Old Arno”), and Laurier Acquisition, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (“Laurier Acquisition”), on June 3, 2008, Laurier Acquisition merged with and into Old Arno, with Old Arno remaining as the surviving corporation and a wholly-owned subsidiary of Laurier. Immediately following this merger, Old Arno merged with and into Laurier and Laurier’s name was changed to Arno Therapeutics, Inc. These two merger transactions are hereinafter collectively referred to as the “Merger.” Immediately following the Merger, the former stockholders of Old Arno collectively held 95% of the outstanding common stock of Laurier, assuming the issuance of all shares issuable upon the exercise of outstanding options and warrants, and all of the officers and directors of Old Arno in office immediately prior to the Merger were appointed as the officers and directors of Laurier immediately following the Merger. Further, Laurier was a non-operating shell company prior to the Merger. The merger of a private operating company into a non-operating public shell corporation with nominal net assets is considered to be a capital transaction in substance, rather than a business combination, for accounting purposes. Accordingly, the Company treated this transaction as a capital transaction without recording goodwill or adjusting any of its other assets or liabilities. All costs incurred in connection with the Merger have been expensed. Upon completion of the Merger, the Company adopted Old Arno’s business plan.

## 2. LIQUIDITY AND CAPITAL RESOURCES

Cash resources as of December 31, 2015 were approximately $0.1 million, compared to approximately $7.9 million as of December 31, 2014. Based on resources at December 31, 2015, including the proceeds received from its recent financing transactions and the current plan of expenditure for continuing the development of the Company’s current product, the Company believes that it has sufficient capital to fund its operations through approximately May 2016. The Company will need substantial additional financing in order to fund its operations beyond such period and thereafter until it can achieve profitability, if ever. The Company depends on its ability to raise additional funds through various potential sources, such as equity and debt financing, or from a transaction in which it would license rights to its product candidates to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

The long-term success of the Company depends on its ability to develop new products to the point of regulatory approval and subsequent revenue generation and, accordingly, to raise enough capital to finance these developmental efforts. Management plans to raise additional capital either by selling shares of its stock or other securities, issuing additional indebtedness or by licensing the rights to one or more of its product candidates to finance the continued operating and capital requirements of the Company. Amounts raised will be used to further develop the Company's product candidates, acquire rights to additional product candidates and for other working capital purposes. While the Company will extend its best efforts to raise additional capital to fund all operations through May 2016 and beyond, management can provide no assurances that the Company will be successful in raising sufficient funds.

In addition, to the extent that the Company raises additional funds by issuing shares of its common stock or other securities convertible or exchangeable for shares of common stock, stockholders will experience dilution, which may be significant. In the event the Company raises additional capital through debt financings, the Company may incur significant interest expense and become subject to covenants in the related transaction documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates, or grant licenses on terms that may not be favorable to the Company. Any or all of the foregoing may have a material adverse effect on the Company's business and financial performance.

**2. LIQUIDITY AND CAPITAL RESOURCES** (Continued)

These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments that might result from the inability of the Company to continue as a going concern.

**3. THE MERGER AND BASIS OF PRESENTATION**

The accompanying audited financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and the instructions to Form 10-K promulgated by the Securities and Exchange Commission ("SEC").

**(a) Description of the Merger and Private Placement Offering**

The Company completed the Merger on June 3, 2008. In accordance with the terms of the Merger, each share of common stock of Old Arno that was outstanding immediately prior to the Merger was exchanged for 1.99377 shares of the Company's common stock. In addition, all securities convertible into or exercisable for shares of Old Arno common stock outstanding immediately prior to the Merger were cancelled, and the holders thereof received similar securities convertible into or exercisable for the purchase of an aggregate of 1,611,760 shares of the Company's common stock. In consideration for their shares of the Company's pre-merger common stock, the Company's shareholders received an aggregate of 19,291,824 shares of Laurier common stock. Immediately prior to the effective time of the Merger, 1,100,200 shares of Laurier's common stock were issued and outstanding. Upon completion of the Merger, the Old Arno shareholders owned approximately 95% of the Company's issued and outstanding common stock, assuming the exercise of all of the issued and outstanding common stock options and warrants.

Following the Merger, the business conducted by the Company is the business conducted by Old Arno prior to the Merger. In addition, the directors and officers of Laurier were replaced by the directors and officers of Old Arno.

As a condition and immediately prior to the closing of the Merger, on June 2, 2008, Old Arno completed a private placement of its equity securities whereby it received gross proceeds of approximately $17,732,000 through the sale of approximately 3,691,900 shares of Old Arno Common Stock to selected accredited investors, which shares were exchanged for approximately 7,360,700 shares of Company Common Stock after giving effect to the Merger.

Contemporaneously with the June 2008 private placement, the Old Arno's outstanding 6% Notes converted into 984,246 shares of Old Arno's common stock and the holders of the Notes received warrants to purchase an aggregate of 98,409 shares of Old Arno common stock at an exercise price equal to $4.83 per share. The shares issued upon conversion were exchanged for an aggregate of approximately 1,962,338 shares of the Company's Common Stock and the warrants were exchanged for five-year warrants to purchase an aggregate of approximately 196,189 shares of the Company's Common Stock at an exercise price equal to $2.42 per share.

All references to share and per share amounts in these financial statements have been restated to retroactively reflect the number of common shares of Arno common stock issued pursuant to the Merger.

**(b) Accounting Treatment of the Merger; Financial Statement Presentation**

The Merger was accounted for as a reverse acquisition pursuant to Accounting Standards Codification ("ASC") 805-40-25, which provides that the "merger of a private operating company into a non-operating public shell corporation with nominal net assets typically results in the owners and management of the private company having actual or effective operating control of the combined company after the transaction, with the shareholders of the former public shell continuing only as passive investors. These transactions are considered by the Securities and Exchange Commission to be capital transactions in substance, rather than business combinations. That is, the transaction is equivalent to the issuance of stock by the private company for the net monetary assets of the shell corporation, accompanied by a recapitalization." Accordingly, the Merger has been accounted for as a recapitalization, and, for accounting purposes, Old Arno is considered the acquirer in a reverse acquisition.

**3. THE MERGER AND BASIS OF PRESENTATION** (Continued)

Laurier's historical accumulated deficit for periods prior to June 3, 2008, in the amount of $120,538, was eliminated against additional-paid-in-capital, and the accompanying financial statements present the previously issued shares of Laurier common stock as having been issued pursuant to the Merger on June 3, 2008. The shares of common stock of the Company issued to the Old Arno stockholders in the Merger are presented as having been outstanding since August 2005 (the month when Old Arno first sold its equity securities).

Because the Merger was accounted for as a reverse acquisition under GAAP, the financial statements for periods prior to June 3, 2008 reflect only the operations of Old Arno.

**(c) Reverse Stock Split**

Effective as of the close of business on October 29, 2013, the Company amended its Amended and Restated Certificate of Incorporation to effect a combination ("Reverse Stock Split") of the Common Stock at a ratio of one-for-eight. All historical share and per share amounts have been adjusted to reflect the Reverse Stock Split.

**4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**(a) Use of Estimates**

The preparation of financial statements in conformity with GAAP requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Estimates and assumptions principally relate to services performed by third parties but not yet invoiced, estimates of the fair value and forfeiture rates of stock options issued to employees, directors and consultants, valuation of derivatives and estimates of the probability and potential magnitude of contingent liabilities. Actual results could differ from those estimates.

**(b) Cash and Cash Equivalents**

The Company considers all highly liquid investments with a remaining maturity of three months or less at the time of acquisition to be cash equivalents.

**(c) Convertible Notes Financing Fees**

Finance costs relating to the convertible notes issued are recorded as a direct reduction of the liability and amortized to interest expense over the expected term using the effective interest method.

**(d) Prepaid Expenses**

Prepaid expenses consist of payments made in advance to vendors relating to service contracts for clinical trial development, insurance policies and license fees. These advanced payments are amortized to expense either as services are performed or over the relevant service period using the straight line method.

**(e) Property and Equipment**

Property and equipment consist primarily of furnishings, fixtures, leasehold improvements and computer equipment and are recorded at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation of property and equipment is provided for by the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter.

| **Description** | **Estimated Useful Life** |
|---|---|
| Office equipment and furniture | 5 to 7 years |
| Leasehold improvements | 3 years |
| Computer equipment | 3 years |
| Equipment under capitalized lease | Over life of lease |

**4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (Continued)

**(f) Fair Value of Financial Instruments**

The Company measures fair value in accordance with generally accepted accounting principles. Fair value measurements are applied under other accounting pronouncements that require or permit fair value measurements. Financial instruments included in the Company's balance sheets consist of cash and cash equivalents, accounts payable, accrued expenses, due to related parties, and derivative liability. The carrying amounts of these instruments reasonably approximate their fair values due to their short-term maturities.

**(g) Convertible Debentures and Warrant Liability**

The Company accounts for the convertible debentures and warrants issued in connection with the 2013 Purchase Agreement, the 2012 Purchase Agreement and the 2010 Purchase Agreement (see Note 10) in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company classify the warrant instrument as a liability at its fair value and adjusts the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The fair value of warrants issued by the Company, in connection with private placements of securities, has been estimated using a Monte Carlo simulation model and, in doing so, the Company's management utilized a third-party valuation report. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices and minimizes standard error.

**(h) Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions and is insured to the maximum limitations. Balances in these accounts may exceed federally insured limits at times, which expose the Company to institutional risk.

**(i) Research and Development**

Research and development costs are charged to expense as incurred. Research and development includes employee costs, fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated executive, human resources and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

**(j) Stock-Based Compensation**

Stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the required service period, which is generally equal to the vesting period. Share-based compensation is recognized only for those awards that are ultimately expected to vest.

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company's Scientific Advisory Board) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

**4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (Continued)

**(k) Basic and Diluted Income/(Loss) per Common Share**

Basic net income/(loss) per share is calculated based on the weighted-average number of shares of common stock outstanding during the period. Diluted net income per share is calculated based on the weighted-average number of shares of common stock and other dilutive securities outstanding during the period. The potential dilutive shares of common stock resulting from the assumed exercise of stock options and warrants are determined under the treasury stock method.

The following table is a reconciliation of the numerator and denominator used in the calculation of basic and diluted net income/(loss) per share.

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Numerator: | | |
| Net income/(loss) | $(11,507,963) | $7,770,767 |
| Denominator: | | |
| Weighted-average shares of common stock outstanding used in the calculation of basic net income/(loss) per share | 20,408,616 | 20,381,554 |
| Effect of dilutive securities: | | |
| Warrants to purchase common stock | - | 4,428,441 |
| Weighted-average shares of common stock outstanding used in the calculation of diluted net income/(loss) per share | 20,408,616 | 24,809,995 |

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive.

As of December 31, 2015 and 2014, potentially dilutive securities include:

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Warrants to purchase common stock | 4,455,231 | 4,455,231 |

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted net income/(loss) per share if their effect is anti-dilutive. In addition to the potentially dilutive securities, the aggregate number of common equivalent shares (related to options, warrants and convertible debentures) that have been excluded from the computations of diluted net income/(loss) per common share at December 31, 2015 and 2014 were 30,563,107 and 50,867,639, respectively, as their exercise prices are greater than the fair market price per common share as of December 31, 2015 and 2014, respectively.

**4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (Continued)

**(l) Comprehensive Loss**

The Company has no components of other comprehensive loss other than its net loss, and accordingly, comprehensive loss is equal to net loss for all periods presented.

**(m) Income Taxes**

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the period in which the differences are expected to affect taxable income. The Company provides a valuation allowance when it appears more likely than not that some or all of the net deferred tax assets will not be realized. The Company has not performed an Internal Revenue Section 382 limitation study. Depending on the outcome of such study, the gross amount of net operating losses recognized in future tax periods could be limited.

A tax position is recognized as a benefit only if it is “more likely than not” that the tax position would be sustained in a tax examination, with a tax examination being presumed to occur. The amount recognized is the largest amount of tax benefit that is greater than 50% likely of being realized on examination. For tax positions not meeting the “more likely than not” test, no tax benefit is recorded.

The Company’s policy is to include interest and penalties related to unrecognized tax benefits within the Company’s provision for (benefit from) income taxes. The Company recognized no amounts for interest and penalties related to unrecognized tax benefits in 2015 and 2014 respectively. In addition, the Company had no amounts accrued for interest and penalties as of December 31, 2015 and 2014, respectively.

**(n) Recently Issued Accounting Pronouncements**

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, “Presentation of Financial Statements-Going Concern (Topic 205-40)” (“ASU 2014-15”). Under the standard, management is required to evaluate for each annual and interim reporting period whether it is a probable that the entity will not be able to meet its obligations as they become due within one year after the date that financial statements are issued, or are available to be issued, where applicable. ASU 2014-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The Company will be evaluating the impact, if any, that the standard will have on its financial condition, results of operations, and disclosures in the near future.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, “Interest- Imputation of Interest (Subtopic 835-30)” (“ASU 2015-03”). This standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those years. Accordingly, the standard is effective for the Company on December 15, 2015. The Company adopted ASU 2015-03 as for the fiscal year 2015 and has reported financing costs as a direct reduction from the carrying amount of convertible notes. The Company’s addition of the standard did not have a material impact on its financial condition, results of operations and disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, “Balance Sheet Classification of Deferred Taxes” (“ASU 2015-17”). The new standard requires all companies to prospectively classify all deferred tax assets and liabilities as noncurrent on the balance sheet. ASU 2015-17 will be effective for public entities on January 1, 2017. However, early adoption is permitted. The Company is evaluating the potential impact of adopting this standard on its financial statements.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01, “Financial Instruments” (“ASU 2016-01”). Equity investments not accounted for under the equity method of accounting will be measured at fair value, with changes in fair value recognized in current earnings. ASU 2016-01 becomes effective for fiscal years beginning after December 15, 2017. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The Company does not believe the adoption of this standard will have a material impact on its financial statements, results of operations or related financial statement disclosures.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). Leasees will need to recognize virtually all of their leases on the balance sheet, by recording a right-of-use asset and lease liability. ASU 2016-02 becomes effective for the Company on January 1, 2019, and early adoption is permitted upon issuance. The Company is evaluating the potential impact of adopting this standard on its financial statements.

**5. PROPERTY AND EQUIPMENT**

Property and equipment as of December 31, 2015 and 2014 consist of the following:

| | 2015 | 2014 |
|---|---|---|
| Computer equipment and software | $17,721 | $17,721 |
| Office furniture and equipment | 72,338 | 72,338 |
| Leasehold improvements | 8,449 | 8,449 |
| Capital leases- equipment | 11,500 | 11,500 |
| Total property and equipment | 110,008 | 110,008 |
| Accumulated depreciation | (86,905 ) | (79,278 ) |
| Total property and equipment, net | $23,103 | $30,730 |

Depreciation expense for the years ended December 31, 2015 and 2014 was $7,627 and $12,586, respectively.

**6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY**

**License Agreements**

***Onapristone License Agreement***

The Company's rights to onapristone are governed by a license agreement with Invivis Pharmaceuticals, Inc. ("Invivis"), dated February 13, 2012. Under this agreement, the Company holds an exclusive, royalty-bearing license for the rights to commercialize onapristone for all therapeutic uses. The license agreement provides the Company with worldwide rights to develop and commercialize onapristone with the exception of France; provided, that the Company has an option to acquire French commercial rights from Invivis upon notice to Invivis together with additional consideration.

The onapristone license agreement provides the Company with exclusive, worldwide rights to a United States provisional patent application that relates to assays for predictive biomarkers for anti-progestin efficacy. The Company intends to expand its patent portfolio by filing additional patent applications covering the use of onapristone and/or a companion diagnostic product. If the pending patent application issues, the issued patent would be scheduled to expire in 2031.

The Company made a one-time cash payment of $500,000 to Invivis upon execution of the license agreement on February 13, 2012. Additionally, Invivis will receive performance-based cash payments of up to an aggregate of $15.1 million upon successful completion of clinical and regulatory milestones relating to onapristone, which milestones include the marketing approval of onapristone in multiple indications in the United States or the European Union as well as Japan. The first milestone was due upon the dosing of the first patient in a pharmacokinetic study and was achieved during August 2013 and the Company made a $150,000 payment to Invivis during October 2013. The Company made its next milestone payment of $100,000 to Invivis upon the dosing of the first subject in the first Company-sponsored Phase I clinical trial of onapristone in January 2014. A milestone payment of $350,000 for the enrollment of the first patient in a Phase II clinical trial sponsored by Arno was paid in July 2015. In addition, the Company will pay Invivis low single digit sales royalties based on net sales of onapristone by the Company or any of its sublicensees. Pursuant to a separate services agreement which expired in April 2014, Invivis provided the Company with certain clinical development support services, which includes the assignment of up to two full-time employees to perform such services, in exchange for a monthly cash payment of approximately $70,833. Effective April 1, 2014, the Company renewed the services agreement for a period of one year for a monthly cash payment of $50,000 and certain other performance based milestones. The services agreement was not renewed upon its expiration on April 1, 2015.

Under the license agreement with Invivis, the Company also agreed to indemnify and hold Invivis and its affiliates harmless from any and all claims arising out of or in connection with the production, manufacture, sale, use, lease, consumption or advertisement of onapristone, provided, however, that the Company shall have no obligation to indemnify Invivis for claims that (a) any patent rights infringe third party intellectual property, (b) arise out of the gross negligence or willful misconduct of Invivis, or (c) result from a breach of any representation, warranty confidentiality obligation of Invivis under the license agreement. The license agreement will terminate upon the later of (i) the last to expire valid claim contained in the patent rights, and (ii) February 13, 2032. In general, Invivis may terminate the license agreement at any time upon a material breach by the Company to the extent the Company fails to cure any such breach within 90 days after receiving notice of such breach or in the event the Company files for bankruptcy. The Company may terminate the agreement for any reason upon 90 days' prior written notice.

**6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY** (Continued)

***AR-12 and AR-42 License Agreements***

The Company's rights to both AR-12 and AR-42 are governed by separate license agreements with The Ohio State University Research Foundation ("Ohio State") entered into in January 2008. Pursuant to each of these agreements, Ohio State granted the Company exclusive, worldwide, royalty-bearing licenses to commercialize certain patent applications, know-how and improvements relating to AR-12 and AR-42 for all therapeutic uses.

In 2008, pursuant to the Company's license agreements for AR-12 and AR-42, the Company made one-time cash payments to Ohio State in the aggregate amount of $450,000 and reimbursed it for past patent expenses. Additionally, the Company is required to make performance-based cash payments upon successful completion of clinical and regulatory milestones relating to AR-12 and AR-42 in the United States, Europe and Japan. The license agreements for AR-12 and AR-42 provide for aggregate potential milestone payments of up to $6.1 million for AR-12, of which $5.0 million is due only after marketing approval in the United States, Europe and Japan, and $5.1 million for AR-42, of which $4.0 million is due only after marketing approval in the United States, Europe and Japan. In September 2009, the Company paid Ohio State a milestone payment upon the commencement of the first Company-sponsored Phase I clinical study of AR-12. The first milestone payment for AR-42 will be due when the first patient is dosed in the first Company-sponsored clinical trial, which is not expected to occur in 2013. Pursuant to the license agreements for AR-12 and AR-42, the Company must pay Ohio State royalties on net sales of licensed products at rates in the low-single digits. To the extent the Company enters into a sublicensing agreement relating to either or both of AR-12 or AR-42, the Company will be required to pay Ohio State a portion of all non-royalty income received from such sublicensee. The Company was not required to make any milestone payments during 2015 and does not expect to be required to make any milestone payments under these license agreements during 2016.

The license agreements with Ohio State further provide that the Company will indemnify Ohio State from any and all claims arising out of the death of or injury to any person or persons or out of any damage to property, or resulting from the production, manufacture, sale, use, lease, consumption or advertisement of either AR-12 or AR-42, except to the extent that any such claim arises out of the gross negligence or willful misconduct of Ohio State. The license agreements for AR-12 and AR-42 each expire on the later of (i) the expiration of the last valid claim contained in any licensed patent and (ii) 20 years after the effective date of the license. Ohio State will generally be able to terminate either license upon the Company's breach of the terms of the license to the extent the Company fails to cure any such breach within 90 days after receiving notice of such breach or the Company files for bankruptcy. The Company may terminate either license upon 90 days prior written notice.

**7. ACCRUED LIABILITIES**

Accrued liabilities as of December 31, 2015 and 2014 consist of the following:

| | 2015 | 2014 |
|---|---|---|
| Accrued research and development expenses | $902,723 | $744,240 |
| Accrued compensation and related benefits | 197,457 | 407,497 |
| Accrued severance | - | 250,605 |
| Accrued interest on convertible notes | 24,510 | - |
| Accrued other expenses | - | 7,951 |
| | $1,124,690 | $1,410,293 |

**8. CONVERTIBLE NOTES PAYABLE**

On October 21, 2015, the Company issued a 6% convertible promissory note (the "6% Note") in the principal amount of $2,100,000 with an original maturity date of October 21, 2016. The 6% Note was mandatorily convertible into shares of the Company's equity securities upon the closing of a financing in which the Company received cumulative gross proceeds of at least $3,500,000 (a "Qualified Financing"), including the $2,100,000 from notes purchase, through the issuance of shares of its equity securities or any securities convertible or exchangeable for equity securities, of one or more series ("Equity Securities"). Contemporaneously with the closing of a Qualified Financing, the outstanding principal of the 6% Note and all accrued but unpaid interest would automatically convert into the same kind of validly issued, fully paid and non-assessable Equity Securities as issued in the Qualified Financing at a conversion price equal to the per share or unit purchase price of the Qualified Financing. The Company incurred $12,528 of issuance costs related to the 6% Note.

The principal balance, unamortized financing costs and net carrying amount of the 6% Note was as follows at December 31, 2015:

| | Principal | Unamortized Debt Issuance Costs | Net Carrying Amount |
|---|---|---|---|
| 6% convertible notes, due October 21, 2016 | $2,100,000 | $ 10,091 | $ 2,089,909 |

As of December 31, 2015, the Company had $24,510 in accrued and unpaid interest. See Note 14 for the subsequent conversion of the 6% Note in January 2016.

**9. FAIR VALUE OF FINANCIAL INSTRUMENTS**

The Company defines fair value as the amount at which an asset (or liability) could be bought (or incurred) or sold (or settled) in a current transaction between willing parties, that is, other than in a forced or liquidation sale. The fair value estimates presented in the table below are based on information available to the Company as of December 31, 2015.

The accounting standard regarding fair value measurements discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The standard utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The

following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The Company has determined the fair value of certain liabilities using the market approach. The following table presents the Company's fair value hierarchy for these assets measured at fair value on a recurring basis as of December 31, 2015:

**9. FAIR VALUE OF FINANCIAL INSTRUMENTS** (Continued)

| | Fair Value December 31, 2015 | Quoted Market Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Liabilities: | | | | |
| Warrant liability - 2012 Series A | $ 1,753,969 | $ - | $ - | $ 1,753,969 |
| Warrant liability - 2012 placement agent | 7,661 | - | - | 7,661 |
| Warrant liability - 2013 Series D | 2,985,512 | - | - | 2,985,512 |
| Warrant liability - 2013 placement agent | 3,545 | - | - | 3,545 |
| Total | $ 4,750,687 | $ - | $ - | $ 4,750,687 |

The following table presents the Company's fair value hierarchy for these assets measured at fair value on a recurring basis as of December 31, 2014:

| | Fair Value December 31, 2014 | Quoted Market Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Liabilities: | | | | |
| Warrant liability - 2010 Class B | $ 28,066 | $ - | $ - | $ 28,066 |
| Warrant liability - 2012 Series A&B | 3,520,319 | - | - | 3,520,319 |
| Warrant liability - 2012 placement agent | 67,246 | - | - | 67,246 |
| Warrant liability - 2013 Series D&E | 3,036,986 | - | - | 3,036,986 |
| Warrant liability - 2013 placement agent | 18,907 | - | - | 18,907 |
| Total | $ 6,671,524 | $ - | $ - | $ 6,671,524 |

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**9. FAIR VALUE OF FINANCIAL INSTRUMENTS** (Continued)

The following table provides a summary of changes in fair value of the Company's liabilities, as well as the portion of losses included in income attributable to unrealized depreciation that relate to those liabilities held at December 31, 2015:

**Fair Value Measurement Using Significant Unobservable Inputs (Level 3)**

| | Total Warrant Liability | 2013 Series E | 2013 Series D | 2013 Placement Agent | 2012 Series B | 2012 Series A | 2012 Placement Agent | 2010 Class B |
|---|---|---|---|---|---|---|---|---|
| Balance at January 1, 2014 | $35,864,881 | $5,855,206 | $12,482,527 | $98,080 | $2,816,676 | $13,887,307 | $362,633 | $362,452 |
| Total gains or losses: | | | | | | | | |
| Unrealized appreciation | (29,193,357) | (5,829,469) | (9,471,278) | (79,173) | (2,804,295) | (10,379,369) | (295,387) | (334,386) |
| Balance at December 31, 2014 | $6,671,524 | $25,737 | $3,011,249 | $18,907 | $12,381 | $3,507,938 | $67,246 | $28,066 |
| Total gains or losses: | | | | | | | | |
| Unrealized appreciation | (1,920,837) | (25,737) | (25,737) | (15,362) | (12,381) | (1,753,969) | (59,585) | (28,066) |
| Balance at December 31, 2015 | $4,750,687 | $- | $2,985,512 | $3,545 | $- | $1,753,969 | $7,661 | $- |
| Value per Warrant | $0.202 | $- | $0.232 | $0.054 | $- | $0.170 | $0.027 | $- |

Significant assumptions used at December 31, 2015 and 2014 for the warrants and embedded conversion discount derivative liability of the Debentures are as follows:

| | December 31, 2015 | | December 31, 2014 | |
|---|---|---|---|---|
| Volatility | 162 | % | 173 | % |
| Risk-free interest rate | 1.38 | % | 1.65 | % |

**10. STOCKHOLDERS' EQUITY**

**Common Stock**

As of December 31, 2015, the Company had 20,408,616 shares of common stock issued and outstanding and approximately 35,018,338 shares of common stock reserved for issuance upon the exercise of outstanding options and warrants.

On October 29, 2013, the Company entered into a Securities Purchase Agreement (the "2013 Purchase Agreement") with certain purchasers identified therein (the "Purchasers") pursuant to which the Company sold and the Purchasers purchased, an aggregate of 12,868,585 units of the Company's securities (the "Units"), with each Unit consisting of the following:

(i) either (a) one share of common stock (each a "Share," and collectively, the "Shares"), or (b) a five-year common stock warrant to purchase one share of common stock (collectively, the "Series C Warrant Shares") at an exercise price of $0.01 per share (collectively, the "Series C Warrants");

(ii) a five-year warrant to purchase one share of common stock (collectively, the "Series D Warrant Shares") at an exercise price of $4.00 per share (collectively, the "Series D Warrants"); and

(iii) a warrant, expiring on October 31, 2014, to purchase one share of common stock (collectively, the "Series E Warrant Shares," and together with the Series C Warrant Shares and the Series D Warrant Shares, the "Warrant Shares") at an exercise price of $2.40 per share (collectively, the "Series E Warrants," and together with the Series C Warrants and the Series D Warrants, the "2013 Warrants").

**10. STOCKHOLDERS' EQUITY** (Continued)

The Company sold and issued 8,413,354 Units consisting of Shares, Series D Warrants and Series E Warrants at a purchase price of $2.40 per Unit, and 4,455,231 Units consisting of Series C Warrants, Series D Warrants and Series E Warrants at a purchase price of $2.39 per Unit, for total gross proceeds to the Company of $30.84 million, before deducting fees and other transaction related expenses of approximately $760,000. A closing of the sale of 12,826,752 Units was completed on October 29, 2013, and the sale of the remaining 41,833 Units was completed on October 30, 2013.

The Purchase Agreement contains customary representations, warranties and covenants by each of the Company and the Purchasers. In addition, the Purchase Agreement provides that each Purchaser has a right, subject to certain exceptions described in the agreement, to participate in future issuances of equity and debt securities by the Company for a period of 18 months following the effective date of the Registration Statement (defined below).

Contemporaneously with the entry into the Purchase Agreement, and as contemplated thereby, the Company entered into a Registration Rights Agreement with the Purchasers. Pursuant to the terms of the Registration Rights Agreement, the Company agreed to file, on or before December 30, 2013 (the "Filing Date"), a registration statement under the Securities Act covering the resale of the Shares and Warrant Shares (the "Registration Statement"), and to cause such Registration Statement to be declared effective by the Commission as soon as practicable thereafter, but not later than 120 days following the date of the Registration Rights Agreement (the "Effectiveness Date"). The Registration Statement was declared effective on January 27, 2014. The Company is required to maintain the effectiveness of the Registration Statement until all of the shares covered thereby are sold or may be sold pursuant to Rule 144 under the Securities Act without volume or manner of- sale restrictions and without the requirement that the Company be in compliance with the current public information requirements of Rule 144.

**Warrants**

In accordance with the 2010 sale and issuance of Series A preferred stock, the Company issued two-and-one-half-year "Class A" warrants to purchase an aggregate of 152,740 shares of Series A Preferred Stock at an initial exercise price of $8.00 per share (the "2010 Class A Warrants") and five-year Class B warrants to purchase an aggregate of 801,885 shares of Series A Preferred Stock at an initial exercise price of $9.20 per share the "2010 Class B Warrants," and together with the 2010 Class A Warrants, the "2010 Warrants"). Upon the automatic conversion of the Series A Preferred Stock in January 2011, the 2010 Warrants automatically converted to the right to purchase an equal number of shares of common stock. The terms of the warrants contain an anti-dilutive price adjustment provision, such that, in the event the Company issues common shares at a price below the current exercise price of the 2010 Warrants, the exercise price will be decreased pursuant to a customary "weighted-average" formula. In accordance with this provision and as a result of the issuances made pursuant to the 2012 Purchase Agreement and 2013 Purchase Agreement, the

exercise price of the 2010 Class B warrants has been adjusted to $3.55 per share. Because of this anti-dilution provision and the inherent uncertainty as to the probability of future common share issuances, the Black-Scholes option pricing model the Company uses for valuing stock options could not be used. Management used a Monte Carlo simulation model and, in doing so, utilized a third-party valuation report to determine the warrant liability to be approximately $0.0 million at December 31, 2015 and December 31, 2014. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices and minimizes standard error. This valuation is revised on a quarterly basis until the warrants are exercised or they expire with the changes in fair value recorded in other income (expense) on the statement of operations. The 2010 Class A warrants, representing the right to purchase an aggregate of 152,740 shares of common stock, expired unexercised during the year ended December 31, 2013, and the Class B warrants, representing the right to purchase an aggregate of 801,885 shares of common stock, expired unexercised during September 2015.

**10. STOCKHOLDERS' EQUITY** (Continued)

Pursuant to the 2012 Purchase Agreement, the Company issued five-year Series A warrants to purchase an aggregate of approximately 6,190,500 shares of common stock at an initial exercise price of $4.00 per share and 18-month Series B warrants to purchase an aggregate of approximately 6,190,500 shares of common stock at an initial exercise price of $2.40 per share. The terms of the 2012 Warrants contain a "full-ratchet" anti-dilutive price adjustment provision. In accordance with such full-ratchet anti-dilution provision, in the event that the Company sells or issues additional shares of common stock, including securities convertible or exchangeable for common stock (subject to customary exceptions), at a per share price less than the applicable 2012 Warrant exercise price, such warrant exercise price will be reduced to an amount equal to the issuance price of such subsequently issued shares; after such time as the Company has raised at least $12 million in additional equity financing, the 2012 Warrants are subject to further anti-dilution protection based on a weighted-average formula. Further, the anti-dilution provisions of the 2012 Warrants provide that, in addition to a reduction in the applicable exercise price, the number of shares purchasable thereunder is increased such that the aggregate exercise price of the warrants (exercise price per share multiplied by total number of shares underlying the warrants) remained unchanged. Because of this anti-dilution provision and the inherent uncertainty as to the probability of future common share issuances, the Black-Scholes option pricing model the Company uses for valuing stock options could not be used. Management used a Monte Carlo simulation model and, in doing so, utilized a third-party valuation report to determine the warrant liability to be approximately $1.8 million and $3.5 million at December 31, 2015 and December 31, 2014, respectively. The Debentures were converted to common stock in 2013. At the time of the conversion of the Debentures, the expiration date of the 2012 Series B Warrants was extended to October 31, 2014, and was thereafter further extended to January 31, 2015. The 2012 Series B warrants, representing the right to purchase an aggregate of approximately 6,190,500 shares of common stock, expired unexercised on January 31, 2015.

In connection with the 2012 offering of the Debentures and 2012 Warrants, the Company engaged Maxim Group LLC, or Maxim Group, to serve as placement agent. In consideration for its services, the Company paid Maxim Group a placement fee of $1,035,000. In addition, the Company issued to Maxim Partners LLC, or Maxim Partners, an affiliate of Maxim Group, 7,500 shares of common stock and five-year warrants to purchase an additional 283,750 shares of common stock at an initial exercise price of $2.64 per share. The warrants issued to Maxim Partners are in substantially the same form as the Warrants issued to the investors, except that they do not include certain anti-dilution provisions contained in the Warrants. However, the placement warrants do contain a provision that could require the Company to repurchase the warrants from the holder under certain conditions. Management used a Monte Carlo simulation model and, in doing so, utilized a third-party valuation report to determine the warrant liability to be approximately $0.0 million and $0.1 million at December 31, 2015 and December 31, 2014, respectively.

Under the terms of the 2013 Purchase Agreement, each Purchaser had the option to elect to receive a Series C Warrant in lieu of a Share in connection with each Unit it purchased. The Series C Warrants have a five-year term and are exercisable at an initial exercise price of $0.01 per share. The Series D Warrants have a five-year term and are exercisable at an initial exercise price of $4.00 per share, subject to adjustment for stock splits, combinations, recapitalization events and certain dilutive issuances (as described below). The Series E Warrants are exercisable until October 31, 2014 at an initial exercise price of $2.40 per share, subject to adjustment for stock splits, combinations,

recapitalization events and certain dilutive issuances (as described below). The applicable exercise price of the Series D Warrants and Series E Warrants (but not the Series C Warrants) is subject to a weighted-average price adjustment in the event the Company makes future issuances of common stock or rights to acquire common stock (subject to certain exceptions) at a per share price less than the applicable warrant exercise price. Because of this anti-dilution provision and the inherent uncertainty as to the probability of future common share issuances, the Black-Scholes option pricing model the Company uses for valuing stock options could not be used. Management used a Monte Carlo simulation model and, in doing so, utilized a third-party valuation report to determine the warrant liability for the Series D Warrants to be approximately $3.0 million at December 31, 2015 and approximately $3.0 million at December 31, 2014 for the Series D and Series E Warrants. The 2013 Series E Warrants, representing the right to purchase an aggregate of 12,868,585 shares of common stock, expired unexercised on January 31, 2015.

The 2013 Warrants are required to be exercised for cash, provided that if during the term of the warrants there is not an effective registration statement under the Securities Act covering the resale of the shares issuable upon exercise of the warrants, then the warrants may be exercised on a cashless (net exercise) basis.

Below is a table that summarizes all outstanding warrants to purchase shares of the Company’s common stock as of December 31, 2015.

**10. STOCKHOLDERS' EQUITY** (Continued)

| Grant Date | Warrants Issued | Exercise Price | Weighted Average Exercise Price | Expiration Date | Exercised | Warrants Outstanding |
|---|---|---|---|---|---|---|
| 11/26/2012 | 8,822,887 | $ 2.40 | $ 2.40 | 11/26/2017 | - | 8,822,887 |
| 11/26/2012 | 261,250 | $ 2.64 | $ 2.64 | 11/26/2017 | - | 261,250 |
| 12/18/2012 | 1,494,577 | $ 2.40 | $ 2.40 | 12/18/2017 | - | 1,494,577 |
| 12/18/2012 | 22,500 | $ 2.64 | $ 2.64 | 12/18/2017 | - | 22,500 |
| 10/29/2013 | 4,455,231 | $ 0.01 | $ 0.01 | 10/29/2018 | - | 4,455,231 |
| 10/29/2013 | 12,868,585 | $ 4.00 | $ 4.00 | 10/29/2018 | - | 12,868,585 |
| 10/29/2013 | 65,650 | $ 2.64 | $ 2.64 | 10/29/2018 | - | 65,650 |
| | 27,990,680 | | $ 2.76 | | - | 27,990,680 |

**11. STOCK OPTION PLAN**

The Company's 2005 Stock Option Plan (the "Plan") was originally adopted by the Board of Directors of Old Arno in August 2005, and was assumed by the Company on June 3, 2008 in connection with the Merger. After giving effect to the Merger, there were initially 373,831 shares of the Company's common stock reserved for issuance under the Plan. On April 25, 2011, the Company's Board of Directors (the "Board") approved an amendment to the Plan to increase the number of shares of common stock issuable under the Plan to 875,000 shares. On January 14, 2013, the Company's Board of Directors approved an amendment to the Plan to increase the number of shares of common stock issuable under the Plan to 945,276 shares. On October 7, 2013, the Company's Board of Directors adopted an amendment to the Company's 2005 Plan, as amended that increased the number of shares of common stock authorized for issuance thereunder from 945,276 to 11,155,295. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options, (b) stock appreciation rights, (c) stock awards, (d) restricted stock and (e) performance shares.

The Plan is administered by the Board, or a committee appointed by the Board, which determines recipients and types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The term of stock options granted under the Plan cannot exceed 10 years. Options shall not have an exercise price less than the fair market value of the Company's common stock on the grant date, and generally vest over a period of three to four years.

As of December 31, 2015, there are 4,087,657 shares available for future grants and awards under the Plan, which covers stock options, warrants and restricted awards.

During the years ended December 31, 2015 and December 31, 2014 the Company issued the following stock options:

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Options granted | 73,399 | 2,423,742 |

The Company estimated the fair value of each option award granted using the Black-Scholes option-pricing model. The following assumptions were used for the years ended December 31, 2015 and 2014:

**11. STOCK OPTION PLAN** (Continued)

| | Year Ended December 31, | |
|---|---|---|
| | **2015** | **2014** |
| Expected volatility | 82% | 86% - 92% |
| Expected term | 6 years | 6 years |
| Dividend yield | 0.0% | 0.0% |
| Risk- free interest rate | 1.64% | 1.57% - 1.63% |
| Stock price | $0.36 - $0.37 | $0.85 - $2.90 |
| Forfeiture rate | 0.0% | 0.0% |

A summary of the status of the options issued under the Plan at December 31, 2015, and information with respect to the changes in options outstanding is as follows:

| | Number of Shares | Weighted-Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Options outstanding at December 31, 2014 | 7,339,118 | $ 2.59 | $ - |
| Granted | 73,399 | - | - |
| Exercised | - | - | - |
| Cancelled | (384,859 ) | $ 2.51 | - |
| Options outstanding at December 31, 2015 | 7,027,658 | $ 2.57 | $ - |
| Options vested and expected to vest at December 31, 2015 | 7,027,658 | $ 2.57 | $ - |
| Exercisable at December 31, 2015 | 4,975,174 | $ 2.67 | $ - |
| Shares available for grant under the 2005 Plan | 4,087,657 | | |

**11. STOCK OPTION PLAN** (Continued)

The following table summarizes information about stock options outstanding at December 31, 2015:

| | Outstanding | | | Exercisable | |
|---|---|---|---|---|---|
| Exercise Price | Number of Shares | Weighted-Average Remaining Contractual Life (Years) | Weighted-Average Exercise Price | Number of Shares | Weighted-Average Exercise Price |
| $ 0.36 | 48,399 | 9.84 | $ 0.36 | 1,344 | $ 0.36 |
| $ 0.37 | 25,000 | 9.84 | $ 0.37 | - | $ 0.37 |
| $ 0.85 | 136,785 | 8.84 | $ 0.85 | 49,394 | $ 0.85 |
| $ 1.30 | 100,000 | 8.77 | $ 1.30 | 31,250 | $ 1.30 |
| $ 2.23 | 97,757 | 0.25 | $ 2.23 | 97,757 | $ 2.23 |
| $ 2.40 | 5,097,075 | 7.21 | $ 2.40 | 3,752,444 | $ 2.40 |
| $ 2.90 | 1,420,259 | 8.07 | $ 2.90 | 940,602 | $ 2.90 |
| $ 8.00 | 65,000 | 4.57 | $ 8.00 | 65,000 | $ 8.00 |
| $ 19.38 | 37,383 | 2.28 | $ 19.38 | 37,383 | $ 19.38 |
| Total | 7,027,658 | 7.32 | $ 2.57 | 4,975,174 | $ 2.67 |

Stock-based compensation costs under the Plan for the year ended December 31, 2015 and 2014 are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Research and development | $ 804,739 | $ 979,792 |
| General and administrative | 2,668,021 | 3,543,876 |
| Total | $ 3,472,760 | $ 4,523,668 |

The fair value of options vested under the Plan was approximately $4,373,033 and $3,828,561 for the years ended December 31, 2015 and 2014, respectively.

At December 31, 2015, total unrecognized estimated compensation cost related to stock options granted prior to that date was approximately $3,588,276 which is expected to be recognized over a weighted-average vesting period of 2.9 years. This unrecognized estimated employee compensation cost does not include any estimate for forfeitures of performance-based stock options.

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company's Scientific Advisory Board) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model and is expensed as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

**12. INCOME TAXES**

The Company accounts for income taxes using the liability method, which requires the determination of deferred tax assets and liabilities, based on the differences between the financial statement and tax bases of assets and liabilities, using enacted tax rates in effect for the year in which differences are expected to reverse. The net deferred tax asset is adjusted by a valuation allowance, if, based on the weight of available evidence, it is more likely than not that some portion or all of the net deferred tax asset will not be realized. The income tax returns of the Company are subject to examination by federal and state taxing authorities. Such examination could result in adjustments to net income or loss, which changes could affect the income tax liabilities of the Company. The Company's tax returns are open for inspection for all tax years from 2009 to present.

**12. INCOME TAXES** (Continued)

The Company's policy is to include interest and penalties related to unrecognized tax benefits within the Company's provision for (benefit from) income taxes. The Company recognized no amounts for interest and penalties related to unrecognized tax benefits in 2015 and 2014 and, as of December 31, 2015 and 2014, had no amounts accrued for interest and penalties.

At December 31, 2015, the Company had no Federal income tax expense or benefit but did have Federal tax net operating loss carry-forwards of approximately $83.9 million. The federal net operating loss carry-forwards will begin to expire in 2026, unless previously utilized.

Deferred income taxes reflect the net effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets at December 31, 2015 and 2014 are shown below.

| | For Years Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Non-current deferred tax assets: | | |
| Net operating loss carry forwards | $ 33,413,500 | $ 30,133,600 |
| Research tax credit | 3,459,600 | 3,267,000 |
| Accrued Expenses | 80,000 | 267,000 |
| Stock based compensation | 4,194,500 | 2,451,000 |
| Total deferred tax assets | 41,147,600 | 36,118,600 |
| Non-current deferred tax liability: | | |
| Bonus Section 401 adjustment | (30,400) | (61,000) |
| Depreciation and amortization | - | - |
| Total net deferred tax assets | 41,117,200 | 36,057,600 |
| Valuation allowance | (41,117,200) | (36,057,600) |
| Net deferred tax assets | $ - | $ - |

The Company records a valuation allowance for temporary differences for which it is more likely than not that the Company will not receive future tax benefits. At December 31, 2015 and 2014 the Company recorded valuation allowances of $41.1 million and $36.1 million, respectively, representing a change in the valuation allowance of $5.0 million for the previous fiscal year-ends, due to the uncertainty regarding the realization of such deferred tax assets, to offset the benefits of net operating losses generated during those years.

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2015 and 2014 are as follows:

| | 2015 Amount | Rate | 2014 Amount | Rate |
|---|---|---|---|---|
| Federal tax | $(3,912,707) | 34.0 % | $2,642,000 | 34.0 % |
| State tax | (749,087) | 6.5 % | 511,000 | 6.6 % |
| Interest expense | (653,085) | 5.7 % | (11,847,000) | (152.5)% |
| R&D credit | (330,928) | 2.9 % | (527,000) | (6.8)% |
| Other Adjustments | 586,206 | (5.1)% | (1,133,000) | (14.6)% |
| Valuation allowance | 5,059,601 | (44.0)% | 10,354,000 | 133.3 % |
| Net | $- | - | $- | - |

There was no income tax benefit recorded for the years ended December 31, 2015 and 2014.

**13. LEASES, COMMITMENTS AND CONTINGENCIES**

On August 4, 2011, the Company entered into a lease for office space of approximately 4,168 square feet in Flemington, New Jersey (the "Flemington Lease"). The lease commencement date was November 17, 2011, with lease payments beginning in February 2012. The lease expiration date is three years from the rent commencement date. The Company provided a cash security deposit of $10,455, or two months' base rent. On June 17, 2014, the Company entered into an amendment to the lease extending expiration until January 31, 2018. The Company is also responsible for payment of its share of common area maintenance costs and taxes. The aggregate remaining minimum future payments under the Flemington Lease at December 31, 2015 are approximately $136,501 including common area maintenance charges and taxes. The Flemington Lease contains a three-month free rent period and annual escalations, as such, the Company accounts for rent expense on a straight-line basis. The Company recognized $90,571 and $84,833 in rent expense for the Flemington Lease for the years ended December 31, 2015 and 2014, respectively.

Future minimum lease payments under operating leases as of December 31, 2015 are as follows:

Future minimum lease payments under operating leases as of December 31, 2015

| | |
|---|---|
| 2016 | 64,430 |
| 2017 | 66,514 |
| 2018 | 5,557 |
| Total future minimum lease payments | $136,501 |

On November 19, 2014, the Company entered into a lease for office equipment. The lease commencement date was November 25, 2014, with lease payments beginning in December 2014. The lease has an initial term of three years and cannot be cancelled or terminated prior to the end of the initial lease term. After the end of the initial term the company can either enter into a new lease, purchase the equipment or return the equipment. The office equipment lease is classified as a capital lease.

Future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of December 31, 2015 are as follows;

Future minimum lease payments under capital leases as of December 31, 2015

| | |
|---|---|
| 2016 | 4,778 |
| 2017 | 4,380 |
| Total net future minimum lease payments | 9,158 |
| Less: Amount representing interest | (1,235) |
| Present value of net minimum lease payments | $7,923 |

On October 29, 2013, in connection with the entry into the 2013 Purchase Agreement, the Company entered into an agreement (the "OPKO Agreement") with OPKO Health, Inc. ("OPKO") and Frost Group, LLC ("Frost Group"). Under the terms of the OPKO Agreement, as in inducement to the participation by OPKO and Frost Group (or its affiliates and associates) in the purchase and sale of the Units under the Purchase Agreement, the Company granted OPKO with the following rights, so long as OPKO continues to hold at least 3% of the total number of outstanding shares of the Company's common stock, determined on a fully-diluted basis (i.e., assuming the issuance of all shares underlying outstanding options, warrants and other rights to acquire common stock): (1) OPKO shall have the right to appoint a non-voting observer to attend all meetings of the Company's Board of Directors, provided that such appointee enters into a confidentiality agreement with the Company and shall be subject to all applicable Company policies; and (2) OPKO shall have a right of first negotiation that provides it with exclusive rights to negotiate with the company for a 45-day period regarding any potential strategic transactions that the Company's Board of Directors elects to pursue.

**13. LEASES, COMMITMENTS AND CONTINGENCIES** (Continued)

The Company has entered into various contracts with third parties in connection with the development of the licensed technology described in Note 6.

The aggregate minimum commitment under these contracts as of December 31, 2015 is approximately $6.5 million, all expected to be due during 2016 and 2017.

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of December 31, 2015. The Company does not anticipate recognizing any significant losses relating to these arrangements.

**14. SUBSEQUENT EVENTS**

On January 12, 2016, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain purchasers identified therein (the "Purchasers") pursuant to which the Company agreed to sell, and the Purchasers agreed to purchase, an aggregate of 21,153,997 shares of the Company's common stock (the "Shares"), at a purchase price of $0.35 per Share for an aggregate gross proceeds of approximately $7.4 million, including approximately $2.1 million from the automatic conversion of outstanding promissory notes and accrued interest, as described below. The Purchase Agreement contains customary representations, warranties and covenants by each of the Company and the Purchasers. The purchase and sale of the shares was completed on January 12, 2016.

The number of Shares sold pursuant to the Purchase Agreement included an aggregate of 6,081,858 Shares that were issued upon the automatic conversion of the Company's 6% Notes. The 6% Notes were originally issued in the principal amount of $2.1 million on October 21, 2015, and such principal amount and $28,652 of accrued interest were converted into Shares.

The Purchasers included several officers and directors of the Company, or entities affiliated with officers and directors of the Company All such officers and directors made such investment on the same terms as all other Purchasers under the Purchase Agreement.

In connection with the entry into the Purchase Agreement, and as contemplated thereby, on January 12, 2016, the Company entered into a Registration Rights Agreement with the Purchasers. Pursuant to the terms of the Registration Rights Agreement, the Company agreed to file, on or before March 12, 2016 (the "Filing Date"), a registration statement under the Securities Act covering the resale of the Shares (the "Registration Statement"), and to cause such Registration Statement to be declared effective by the Commission as soon as practicable thereafter, but not later than 120 days following the date of the Registration Rights Agreement (the "Effectiveness Date"). If the Company does not file the Registration Statement by the Filing Date or obtain its effectiveness by the Effectiveness Date, then the Company is required to pay liquidated damages to the Purchasers in an amount equal to 1% of the aggregate purchase price paid by such Purchaser for the Shares per month until the Registration Statement is filed or declared effective, as applicable, subject to a maximum of 10% of the aggregate purchase price paid by each Purchaser for the Units. The Company is required to maintain the effectiveness of the Registration Statement until all of the shares covered thereby are sold or may be sold pursuant to Rule 144 under the Securities Act without volume or manner-of-sale restrictions and without the requirement that the Company be in compliance with the current public information requirements of Rule 144. The Company filed the Registration Statement with the Commission on March 11, 2016, satisfying its obligation to file the Registration Statement on or before the Filing Date.

**14. SUBSEQUENT EVENTS** (Continued)

On March 14, 2016, the Board of the Company adopted the Company's 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan replaces the Company's 2005 Stock Option Plan, which will expire March 31, 2016, and no further awards will be made pursuant to such plan. The Board will initially be the administrator of the 2016 Plan, but the Board may delegate the administration of the 2016 Plan to the Company's Compensation Committee. The Board and any Committee to which it may delegate the administration of the 2016 Plan are collectively referred to in the 2016 Plan as the "Administrator."

Any employee, director, or consultant may participate in the 2016 Plan; provided, however, that only employees are eligible to receive incentive stock options. Additionally, the Company may grant certain performance-based awards to "covered employees" in compliance with Section 162(m) of the Internal Revenue Code. These covered employees include our executive officers.

The stock to be awarded or optioned under the 2016 Plan will consist of authorized but unissued or reacquired shares of common stock. The maximum aggregate number of shares of common stock reserved and available for awards under the 2016 Plan is 9,000,000 shares; provided, that all shares of stock reserved and available under the 2016 Plan will constitute the maximum aggregate number of shares of stock that may be issued through incentive stock options. No person may be granted options, stock appreciation rights, restricted stock awards, restricted stock units or performance awards under the 2016 Plan for more than 2,000,000 shares of common stock in any calendar year.

The Administrator will adjust the number of shares and share limit described above in the case of a stock dividend, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-off, repurchase or exchange of shares, or other similar corporate transaction where such an adjustment is necessary to prevent dilution or enlargement of the benefits available under the 2016 Plan. Any adjustment determination made by the Administrator will be final, binding and conclusive.

The Administrator may grant awards pursuant to the 2016 Plan until it is discontinued or terminated; provided, however, that incentive stock options may not be granted after March 13, 2026.

**21,153,997 Shares**

**Common Stock**

PROSPECTUS

April 18, 2016