

Arno Therapeutics, Inc  
Form S-1  
December 26, 2012

As filed with the Securities and Exchange Commission on December 26, 2012 Registration No. 333-

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**ARNO THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number)	52-2286452 (I.R.S. Employer Identification No.)
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**200 Route 31 North, Suite 104**

**Flemington, New Jersey 08822**

**(862) 703-7170**

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(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Glenn R. Mattes  
President and Chief Executive Officer  
Arno Therapeutics, Inc.  
200 Route 31 North, Suite 104  
Flemington, NJ 08822  
(862) 703-7170

(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this registration statement, as shall be determined by the selling stockholders identified herein.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If this Form is a post effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer  Accelerated filer   
 Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offer Price Per Share	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common stock, par value \$0.0001 per share	208,815,953	\$ 0.50	\$ 104,407,976.50	\$ 14,241.25

(1) There is also being registered hereunder an indeterminate number of additional shares of common stock as shall be issuable pursuant to Rule 416 to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for purposes of calculating the amount of the registration fee pursuant to Rule 457. The offering price per share and the aggregate offering price are based upon the average of the high and low prices of the registrant's common stock as reported on the OTC Bulletin Board on November 12, 2012, the most recent date on which shares of the registrant's common stock were traded.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SUCH SECTION 8(A), MAY DETERMINE.**

A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

**Subject to completion, dated December 26, 2012**

## **OFFERING PROSPECTUS**

**208,815,953 Shares**

### **Common Stock**

The selling stockholders identified beginning on page 23 of this prospectus are offering on a resale basis a total of 208,815,953 shares of our common stock, of which 74,286,000 shares are issuable upon the conversion of our outstanding 8% Senior Convertible Debentures, 8,389,948 shares are issuable as payment of accrued interest under the debentures, and 126,080,005 shares are issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is quoted on the OTC Bulletin Board under the symbol "ARNI.OB." On \_\_\_\_\_, 2012, the last sale price of our common stock as reported on the OTCBB was \$ .

**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 \_\_\_\_\_, 2013.**

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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," "we," "us," or "our" refer to Arno Therapeutics, Inc., a Delaware corporation.*

### Company Overview

We are a development stage company focused on developing innovative products for the treatment of cancer. The following is a summary of our product development pipeline:

Onapristone – On February 13, 2012, we entered into a license agreement granting us rights to commercially develop onapristone, an anti-progesterone hormone blocker that has been shown to have considerable anti-tumor activity in breast cancer. Onapristone appears to have a unique ability to block the activated progesterone receptor and inhibit tumor growth. Onapristone was originally developed by Schering AG for potential use as a contraceptive and an anti-endocrine treatment of breast cancer. In clinical studies, onapristone has demonstrated a 56% objective response rate as a first line "hormone" treatment of patients with breast cancer. In connection with the development of onapristone, we intend to develop a companion diagnostic product to identify patients who express the activated form of the progesterone receptor and therefore may be more likely to benefit from treatment with onapristone. We intend to conduct pre-clinical toxicology studies and manufacturing activities and to file an investigational new drug application, or IND, or its foreign equivalent in 2013.

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. In preclinical studies, AR-42 has demonstrated greater potency and activity in solid tumors and hematological malignancies when compared to vorinostat (also known as SAHA and marketed as Zolinza® by Merck). These data demonstrate the potent and potential differentiating activity of AR-42. Additionally, pre-clinical findings 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, or AML. AR-42 is currently being studied in an investigator-initiated Phase I/II clinical study in adult subjects with relapsed or refractory hematological malignancies: multiple myeloma, chronic lymphocytic leukemia (CLL), or lymphoma. The recommended Phase II dose, or RP2D, in patients with hematological malignancies has been determined and the expansion phase of the program has been initiated. We expect that the expansion phase of the hematological malignancy cohort will take at least 12 months to complete. The protocol has been amended to include a separate solid tumor dose escalation cohort

and patients are being actively screened to enter into this cohort. In preclinical studies, AR-42 has demonstrated anti-tumor activity in both meningioma and schwannoma. 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 February 2012, the FDA granted two orphan drug designations for AR-42 for the treatment of meningioma and the treatment of schwannoma of the central nervous system. 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. We have also applied to the FDA for orphan drug designation of AR-42 for the treatment of NF2 associated central nervous system tumors.

AR-12 – We are also developing AR-12 as an orally available, targeted anti-cancer agent that has been shown in early pre-clinical studies to inhibit phosphoinositide dependent protein kinase-1, or PDK-1, a protein in the PI3K/Akt pathway that is involved in the growth and proliferation of cells, including cancer cells. 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. Preliminary data demonstrates that AR-12 may inhibit multiple different kinase targets. In May 2009, the FDA accepted our IND for AR-12. We are currently conducting a multi-centered Phase I clinical study of AR-12 in adult patients with advanced or recurrent solid tumors or lymphoma. The Phase I study of AR-12 was originally designed to be conducted in two parts. The first part is a dose-escalating study, which we refer to as the Escalation Phase, primarily designed to evaluate the safety of AR-12 in order to identify the MTD and RP2D for future studies of the compound. We anticipate that the Escalation Phase will be completed in the first quarter of 2013. We also anticipate the determination of an RP2D and MTD with the conclusion of the Escalation Phase in the first quarter of 2013. 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 that has been shown to substantially increase bioavailability in preclinical models.



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.

In May 2009, we voluntarily filed a Form 15 with the Securities and Exchange Commission in order to terminate the registration of our common stock under the Securities and Exchange Act of 1934, as amended, or the Exchange Act. As a result, our obligation to file periodic and other reports under the Exchange Act was suspended. On February 9, 2011, the effective date of the registration statement filed in connection with our September 2010 private placement of Series A Preferred Stock, we again became subject to the reporting requirements of the Exchange Act.

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](http://www.arnothera.com). Information contained in, or accessible through, our website does not constitute a part of this prospectus.

## **Risk Factors**

As with most pharmaceutical 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 are a development stage company with a very 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**

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The selling stockholders identified beginning on page 23 of this prospectus are offering on a resale basis a total of 208,815,953 shares of our common stock, of which 74,286,000 shares are issuable upon the conversion of our outstanding 8% Senior Convertible Debentures, 8,389,948 shares are issuable as payment of accrued interest under the debentures, and 126,080,005 shares are issuable upon the exercise of outstanding warrants. The total value of all the common stock offered pursuant to this prospectus is approximately \$104.4 million, based upon a per share price of \$0.50. Of this total amount, approximately \$37.4 million represents the value of the common stock offered pursuant to this prospectus that is issuable upon the conversion of our outstanding 8% Senior Convertible Debentures. See “Plan of Distribution.”

Common stock offered 208,815,953 shares

Common stock  
outstanding before the  
offering<sup>(1)</sup> 36,364,942 shares

Common stock  
outstanding after the  
offering<sup>(2)</sup> 245,120,895 shares

Use of Proceeds We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which would be used for working capital and other general corporate purposes.

OTC Bulletin Board  
Symbol ARNI.OB

(1) Based on the number of shares outstanding as of December 24, 2012, not including 141,048,053 shares issuable upon exercise of various warrants and options to purchase our common stock, any shares issuable upon the conversion of our outstanding 8% Senior Convertible Debentures, or any shares issuable as payment of accrued interest under the debentures.

(2) Assumes the issuance of all shares offered hereby that are issuable upon the conversion of our outstanding 8% Senior Convertible Debentures or upon exercise of warrants. Also assumes three years of interest accrual under the debentures at the rate of 8% per annum, and our election to pay such accrued interest in the form of additional shares of common stock in lieu of cash. See “*Description of 2012 Debenture and Warrant Offering.*”

## Recent Developments

### *Private Placement of 8% Senior Convertible Debentures and Warrants*

On November 26, 2012, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with a number of institutional and accredited investors pursuant to which we sold in a private placement an aggregate principal amount of \$14,857,200 of our three-year 8% Senior Convertible Debentures, or the Debentures. In accordance with the Purchase Agreement, we also issued to each investor a five-year warrant to purchase, at an initial exercise price of \$0.50 per share, a number of shares of common stock equal to the principal amount of Debentures purchased by such investor divided by \$0.30. We collectively refer to these warrants as the Series A Warrants. In addition to the Series A Warrants, each investor also received an 18-month warrant to purchase, at an initial exercise price of \$0.30 per share, a number of shares of common stock equal to the principal amount of Debentures purchased by such investor divided by \$0.30, which we collectively refer to as the Series B Warrants, and which we collectively refer to together with the Series A Warrants as the Warrants. Pursuant to the Purchase Agreement, we issued to the investors Series A Warrants to purchase an aggregate of 49,524,003 shares of common stock, and Series B Warrants to purchase an aggregate of 49,524,003 shares of common stock. The sale of the Debentures and Warrants, which occurred in two closings on November 26, 2012 and December 18, 2012, resulted in aggregate gross proceeds of approximately \$14.9 million, before deducting placement agent fees and other transaction-related expenses of approximately \$1.2 million. A more detailed description of the terms of the Debentures and Warrants is contained elsewhere in this prospectus under the caption “Description of 2012 Debenture and Warrant Offering”.

Pursuant to the terms of a Registration Rights Agreement entered into on November 26, 2012 in connection with our entry into the Purchase Agreement, we agreed to file a registration statement under the Securities Act of 1933, as amended, covering the resale of: (i) 100% of the shares of our common stock issuable as payment of accrued interest under the Debentures and upon exercise of the Series A Warrants; and (ii) 150% of the shares of our common stock issuable upon conversion of the Debentures and upon exercise of the Series B Warrants. We further agreed to cause such registration statement to be filed with 30 days following the date of the Registration Rights Agreement, or by December 26, 2012, and to cause such registration statement to be declared effective within 60 days following the date of the Registration Rights Agreement, or by January 25, 2013, or, if the Registration Statement is subject to review by the SEC, to cause such registration statement to be declared effective within 120 days following the date of the Registration Rights Agreement, or by March 26, 2013. If such registration statement is not declared effective by the SEC by the applicable date, we agreed to pay liquidated damages to the investors in the amount of 2% of each investor’s aggregate investment amount per month until the registration statement is declared effective. The registration statement of which this prospectus is a part registers the resale of the shares of our common stock issuable upon conversion of the Debentures and upon exercise of the Warrants.

In connection with the private placement, we engaged Maxim Group LLC, or Maxim Group, to serve as placement agent. In consideration for its services, we paid Maxim Group a placement fee of \$1,035,000. In addition, we issued to Maxim Partners LLC, or Maxim Partners, an affiliate of Maxim Group, 60,000 shares of common stock and five-year warrants to purchase an additional 2,270,000 shares of common stock at an initial exercise price of \$0.33 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.

***Increase in Authorized Common Stock***

On November 21, 2012, upon receipt of the requisite stockholder approval, we amended our Amended & Restated Certificate of Incorporation for the purpose of increasing the number of shares of common stock that we are authorized to issue from 80,000,000 shares to 500,000,000 shares.

## 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 will need to raise substantial additional capital to operate our business.***

To date, we have generated no product revenues. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Currently, none of our product candidates are approved for sale by the FDA. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand and, potentially, future offerings of our equity and debt securities. Based on our current development plans, and taking into account the net proceeds from our 2012 offering of Debentures and Warrants, we believe we have cash on hand to fund our operations through approximately the third quarter of 2013. We will 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. There can be no assurance that such additional financing can be obtained on desirable terms, if at all. In addition, changes may occur that would consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates and changes in regulation. Accordingly, we will need additional capital to fund our continuing operations. Since we do not generate any recurring revenue, the most likely sources of such additional capital include private placements of our equity securities, including our common stock, debt financing or funds from a potential strategic licensing or collaboration transaction involving 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 covenants in the related transaction documentation 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. This uncertainty is exacerbated due to the global economic turmoil of the last few years, which continues to severely

restricted access to the U.S. and international capital markets, particularly for small biopharmaceutical and biotechnology companies like us. Accordingly, 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 forced to significantly curtail our planned research and development activities, which will cause a delay in our drug development programs and may severely harm our business.

***We are a development stage company.***

We have not received any operating revenues to date and are in the development stage. You should be aware of the problems, delays, expenses and difficulties encountered by an enterprise in our stage of development, and particularly for companies 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 are not currently profitable and may never become profitable.***

We expect to incur substantial losses and negative operating cash flows for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2011 and 2010, we had a net loss of \$7,909,113 and \$4,023,026, respectively. For the nine months ended September, 2012, we had a net loss of \$5,858,578, and for the period from our inception on August 1, 2005 through September 30, 2012, we had a net loss of \$41,371,578. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses 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.

Further, for the years ended December 31, 2011 and 2010, we had negative cash flows from operating activities of \$6,833,566 and \$3,533,085, respectively. For the nine months ended September, 2012, we had negative cash flows from operating activities of \$6,084,712, and for the period from our inception on August 1, 2005 through September 30, 2012, we had negative cash flows from operating activities of \$34,821,416. We expect to continue to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

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

We are a development stage company 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.

***The relationships between Two River Consulting, Riverbank Capital Securities and certain of our officers and directors may present potential conflicts of interest.***

Arie S. Belldegrun, M.D., our Chairman, David M. Tanen, one of our directors, and Joshua A. Kazam, a co-founder and director of our company until September 2010, are the managing members of Two River Consulting, LLC, or TRC. Mr. Tanen serves as our Secretary and, from June 2009 until April 2011, also served as our President. In June 2009, we entered into a services agreement with TRC pursuant to which it performs various management, clinical development, operational and administrative activities and services for us. As consideration for these services, we paid TRC a monthly cash fee of \$55,000. While the term of the services agreement expired on April 1, 2011, we continue to utilize the services of TRC and TRC is now billing the Company for actual hours worked on a monthly basis. For the second through fourth quarters of 2011, TRC billed us \$287,145 for services rendered, an average of approximately \$31,900 per month. Each of Messrs. Kazam and Tanen, as well as Peter M. Kash, Ed.D., a co-founder and director of our company until April 2011, are also officers and directors of Riverbank, a broker-dealer registered with the Financial Industry Regulatory Agency, or FINRA, which served as placement agent in connection with our September 2010 private placement of Series A Preferred Stock. Scott L. Navins, the Financial and Operations Principal of Riverbank and Vice President – Finance of TRC, serves as our Treasurer.

Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable from a person who is not an affiliate in an arms-length transaction. We believe that the terms of the agreements that we have entered into with TRC and Riverbank satisfy the requirements of Delaware law, but in the event one or more parties challenges the fairness of such terms we may have to expend substantial resources in resolving such challenges and can make no guarantees of the result. Further, none of our affiliates or TRC is obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and the investors should not expect, that any biomedical or pharmaceutical product or technology identified by such affiliates or TRC in the future will be made available to us.

In addition to the relationships and transactions described above, each of Dr. Belldegrun, Dr. Kash, and Messrs. Kazam and Tanen are significant stockholders and serve as officers and directors of other biopharmaceutical and biotechnology companies some of which may be considered a potential competitor of ours. See “Directors and Executive Officers” for additional information about the activities of Dr. Belldegrun and Mr. Tanen. Certain of our other current officers and directors or certain of any officers or directors hereafter appointed may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. There can be no assurance that such other companies will not have interests in conflict with our own.



***We are substantially dependent on the services of TRC and other consultants.***

We have only four employees. We currently rely heavily on TRC to render various management, accounting and administrative activities and services for us. We also 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.***

Although we currently engage TRC to provide personnel to perform a variety of management, accounting and other services on our behalf on a consulting basis, we expect to directly hire employees, including at the senior management level, in the future as we further the development of our clinical programs. As we further the development of our product candidates, we intend to hire employees to perform the services currently being rendered by TRC. 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, which include the persons affiliated with TRC discussed above, beneficially own approximately 83.5% 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.***

The three co-lead investors in our September 2010 private placement, 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") beneficially own approximately 30.5%, 31.8%, and 8.1% of our outstanding common stock, respectively. In addition, 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.

***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 and 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.

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## 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 conversion of our outstanding Debentures and 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.***

The conversion of our outstanding 8% senior convertible debentures in the principal amount of \$14.9 million, or the Debentures, could result in the issuance of up to 49.5 million shares of common stock, assuming the entire amount of the Debentures is converted prior to their maturity dates in November and December 2015. Further, we issued warrants to the holders of the Debentures to purchase an aggregate of 99 million shares of our common stock. Both the conversion prices applicable to the Debentures and the exercise prices applicable to the warrants are subject to adjustment pursuant to certain anti-dilution provisions. The issuance by us of the shares of common stock issuable upon conversion of the Debentures and exercise of the 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 of their dates of issuance, the immediate conversion of the Debentures would result in the issuance by us of approximately 49.5 million shares of our common stock at a conversion price of \$0.30 per share. The exercise of the warrants that we issued to the holders of the Debentures could result in the issuance of up to approximately 99 million shares of common stock. Half of these warrants are initially exercisable at a price per share equal to \$0.50 and the remaining half are exercisable at a price of \$0.30 per share. The conversion price of the Debentures and the exercise prices of the warrants are subject to adjustment, however, 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 conversion or exercise prices. If we issue additional shares of our common stock at a price less than such conversion or exercise prices during the period of time until we have raised an additional \$12 million in aggregate equity financings, the Debenture conversion and warrant exercise prices will be reduced to equal such lower price. To the extent we issue additional shares of our common stock at a price per share less than the applicable Debenture conversion and warrant exercise prices during the period following the date we have raised at least \$12 million of additional equity financing, then the Debenture conversion and warrant exercise prices will be reduced based on a “weighted-average” formula. We expect that we will need substantial additional capital in order to fund our operations during the terms of the Debentures and 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 Debenture conversion and warrant exercise prices, our stockholders could experience a significant dilution of their investment.

The holders of the Debentures and 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 conversion of the Debentures or exercise of the warrants.

***Upon an “event of default” under our outstanding debentures, we may be required to pay an amount in cash significantly exceeding the outstanding principal and accrued interest owed under the debentures.***

Upon an “event of default,” as that term is defined under the Debentures, we are required to pay to the holders an amount in cash equal to the greater of the following:

(i) the outstanding principal amount of the Debentures plus accrued and unpaid interest, divided by (ii) the conversion price in effect on the date of such default, multiplied by (iii) the volume weighted average price, or VWAP, of our common stock on the date of default; or

115% of the outstanding principal amount of the Debentures, plus all accrued and unpaid interest and other costs and expenses owing under the Debentures.

As a result of this formula, the higher our stock price is on the date of an event of default, the greater the cash payment we will be required to make. For example, we currently have approximately \$15 million of principal amount of Debentures outstanding, so if the VWAP of our common stock is \$1.00 at the time of an event of default and the conversion price is then \$0.30, upon an event of default we will be required to make a cash payment of \$50 million (\$15 million divided by 0.30 multiplied by 1.00) to the holders of the debentures without regard to any accrued and unpaid interest. Accordingly, if an event of default occurs under the Debentures, we will incur a substantial liability that would likely cause significant adverse effect on our financial condition. See “Description of 2012 Debenture and Warrant Offering – Description of the 2012 Debentures – Events of Default.”

***The terms of our outstanding 8% senior convertible debentures may make it difficult for us to raise additional capital at times and upon terms we deem advisable.***

Until the 18-month anniversary of the effective date of the registration statement covering the resale of the shares issuable upon conversion of the Debentures, we may not (subject to certain exceptions, including issuances to pursuant to our equity incentive plans, underwritten public offerings and strategic transactions) issue or sell additional shares of our common stock, or securities convertible into or exercisable for common stock without the prior consent of holders of two-thirds of the Debentures. As a result of this provision, our ability to obtain additional capital from future financing transactions, particularly financing transactions structured as a private placement of our common stock, will be subject to the approval of the Debenture holders. If the Debenture holders do not approve of any such proposed issuance, we may not be able to raise the capital necessary to fund our operations, including the further development of our product candidates, at the times or on the terms we deem advisable.

***If we are not able to satisfy our interest payment obligations under the Debentures by issuing shares in lieu of cash payments, we will have less cash to spend on our research and development programs.***

The outstanding principal amount under the Debentures accrues interest at the rate of 8% per annum, payable quarterly in arrears commencing January 1, 2013. Our quarterly interest obligations under the Debentures will be approximately \$300,000. We may elect to pay such interest in kind by issuing shares of its common stock valued at a price per share equal to 85% of the trailing 20-day volume weighted average price of our common stock, provided certain conditions have been satisfied. Those conditions include that the average daily trading volume of our common stock is at least 25,000 shares. The current average daily trading volume of our common stock is less than 1,000

shares. Accordingly, we will be required to pay cash to satisfy our interest obligations for the near future, and possibly beyond, unless and until the trading volume of our common stock increases significantly. To the extent we are required to use our cash resources to satisfy such interest obligations, we will have less capital to devote to our research and development programs and we will more rapidly exhaust our available cash, both of which would be harmful to our business. See “Description of 2012 Debenture and Warrant Offering – Description of the 2012 Debentures – Interest.”

***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 OTC Bulletin Board, or the OTCBB. Stocks traded on the OTCBB 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 the American Stock Exchange in the future, but we cannot assure you that we will be able to meet the initial listing standards of either of those or any other 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.

## **USE OF PROCEEDS**

We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which would be used for working capital and other general corporate purposes.

## **DESCRIPTION OF 2012 DEBENTURE AND WARRANT OFFERING**

### **General**

On November 26, 2012, we entered into a securities purchase agreement with certain accredited investors, whereby the investors acquired in two closings occurring on November 26, 2012 and December 18, 2012, \$14,857,200 of aggregate principal amount of our 8% senior convertible debentures, or the Debentures, in a private placement, which we refer to as the 2012 offering. Additionally, each investor received two series of warrants, referred to as the 2012 Series A Warrants and the 2012 Series B Warrants, to purchase an aggregate of 99,048,007 shares our common stock.

The purchase agreement contains customary representations, warranties and covenants by each of us and the investors. In addition, the purchase agreement provides that each investor has a right, subject to certain exceptions described in the agreement, to participate in future issuances of equity and debt securities by us for a period of 18 months following the effective date of the registration statement (defined below under “—Registration Rights Agreement”). Further, subject to certain exceptions described in the purchase agreement, during such 18-month period, we may not issue or propose to issue any equity securities without the consent of the holders of two-thirds of the outstanding Securities.

### **Description of the 2012 Debentures**

*The following description is qualified in its entirety by the terms and conditions of the Debentures, the form of which is incorporated by reference into the registration statement of which this prospectus forms a part. The following description may not contain all the information with respect to the Debentures that is important to you. We encourage you to read the form of Debenture in its entirety.*

**General**

The Debentures are unsecured obligations, senior to all of our other indebtedness. The Debentures were sold for 100% of their face amount. Debentures having a principal face amount of \$12,705,000 were issued on November 26, 2012 and will mature on November 26, 2015. Debentures having a principal face amount of \$2,152,200 were issued on December 18, 2012 and will mature on December 18, 2015. We may not prepay any outstanding principal prior to the applicable maturity date.

**Interest**

The Debentures accrue interest at an annual rate of 8%, which is payable in cash quarterly in arrears commencing January 1, 2013. We may elect to satisfy these interest payments by issuing shares of our common stock at a value of 85% of the average volume weighted price of our common stock for the 20 consecutive trading days prior to the interest payment date, provided that certain conditions are met, which are referred to as "equity conditions." Equity conditions include the following:

· our having honored all conversions duly requested by the investors;

· our having paid any liquidated damages or other amounts due to the investors under the Debentures;

either (i) a registration statement covering the resale of the shares of common stock issuable upon conversion of the Debentures, including the interest conversion shares in the case of an interest share payment, and the investors are permitted to resell the shares of common stock received upon conversion of any part of the Debentures or (ii) such shares may otherwise be resold by the investors pursuant to Rule 144;

our common stock is trading on a trading market and is listed or quoted for trading on such trading market, which includes the OTC Bulletin Board, on which our common stock is currently eligible for trading;

we have a sufficient number of authorized but unissued shares of common stock for issuance of all shares of common stock underlying the Debentures and the 2012 Warrants;

there is no existing event of default under the Debentures and there is no existing event that would, with the passage of time or giving of notice, constitute an event of default under the Debentures;

we have not publicly announced a pending or proposed fundamental or change of control transaction which has not been consummated or abandoned;



we have not provided any investor with any material, non-public information relating to us;

in the case of a forced conversion (discussed below), the average daily trading volume of our common stock on its principal trading market exceeded 100,000 shares for a the relevant 10 consecutive trading day period described in the Debentures; and

in the case of the issuance of shares in satisfaction of our interest obligation, the average daily trading volume of our common stock on its principal trading market exceeded 25,000 shares for a the relevant 10 consecutive trading day period described in the Debentures.

### *Conversion of Debentures*

The Debentures may be converted by each investor at any time, at the option of such investor, in whole or in part. The Debentures are initially convertible into shares of our common stock, at a per share conversion price equal to \$0.30. Other than with respect to certain excluded issuance of securities described below, the conversion price is subject to full-ratchet anti-dilution protection upon any grant of any right to purchase or any issuance of our common stock and/or securities convertible or exchangeable into our common stock at an effective price per share less than the conversion price of the Debentures then in effect (we refer to each such issuance as a Dilutive Issuance, and each effective price per share in such Dilutive Issuance, as a Dilutive Price). Consequently, upon any Dilutive Issuance (other than with respect to an exempt security), the conversion price of each Debenture would be automatically reduced to the applicable Dilutive Price. However, after such time following the issuances of the Debentures as we have raised an aggregate of \$12 million in gross cash proceeds from the one or more equity financing transactions, the Debenture conversion price is no longer subject to full-ratchet anti-dilution protection. Instead, the Debenture conversion price is subject to a weighted-average anti-dilution which means that the conversion price is reduced on a weighted-average basis by a Dilutive Issuance.

Any shares of our common stock issued or issuable in the following transactions are exempt securities that do not trigger the full-ratchet or weighted-average anti-dilution protection of the Debentures:

Issuances of our common stock pursuant to any board approved employee plan;

Issuances of our common stock upon conversion or exercise of securities outstanding on prior to the issuance of the Debentures (in the form as in effect as of such date);

Issuances of our common stock in connection with acquisitions or strategic transactions to a company (or to the owners of a company) that is an operating company and that provides us with additional benefits in addition to the investment of funds, but excluding a transaction in which we are issuing securities primarily for capital raising

purposes.

We may also force the conversion of the Debentures at our option if each of the equity conditions listed above have been satisfied and, following the effective date of a registration statement covering the resale of the Debenture conversion shares, the volume weighted average price of our common stock exceeds \$1.50 for each of any 10 consecutive trading days.

Debentures issued to many of the investors also include an additional limitation on conversion, which provides that at no time will an investor be entitled to convert any portion of the Debentures, to the extent that after such conversion such investor (together with its affiliates) would beneficially own more than 9.99% of the outstanding shares of our common stock as of such date.

If we fail to timely deliver shares of common stock to an investor following delivery of a conversion notice, we may be liable for liquidated damages to such investor. Our failure to deliver shares in a timely manner also provides the investor with a right to rescind its conversion request.

To the extent an investor does not elect to convert its Debenture as described above, the principal amount of the Debenture not so converted on or prior to the maturity date shall be payable in cash on the maturity date.

### ***Fundamental Transactions***

Upon the occurrence of a fundamental transaction, each investor shall have the right to receive, for each share of our common stock issuable upon conversion of the Debentures immediately prior to such transaction, the number of shares of our common stock, or stock of the successor or acquiring corporation, and any additional consideration receivable as a result of such transaction by a holder of our common stock, which shall be referred to as the alternate consideration. Fundamental transactions include:

our merger or consolidation with or into another person;

our sale, lease, license, assignment, transfer, conveyance or other disposition of substantially all of our assets in one or a series of related transactions;

the completion of a purchase offer, tender offer or exchange offer (whether by us or another person) accepted by the holders of a majority of our outstanding common stock;





any reclassification, reorganization or recapitalization of our common stock or any compulsory share exchange in which our common stock is converted into or exchanged for other securities, cash or property; or

the consummation of a stock or share purchase agreement or other business combination with another person where such other person acquired more than 50% of our outstanding shares of common stock (excluding shares held by such person or persons party to the agreement or combination or associated or affiliated with such person or persons).

The conversion price of the Debentures shall be appropriately adjusted following any fundamental transaction to apply to the alternate consideration received by holders of our common stock thereunder for one share of our common stock.

Additionally, if, at any time while the Debentures are outstanding, we:

pay a stock dividend or otherwise make distributions payable in shares of our common stock on our common stock or common stock equivalents;

subdivide outstanding shares of our common stock into a larger number;

combine outstanding shares of our common stock into a smaller number; or

issue any shares of our capital stock in a reclassification of our common stock, then the conversion price of the Debentures shall be multiplied by a fraction the numerator of which shall be the number of shares of our common stock outstanding immediately prior to the event and the denominator of which shall be the number of shares of our common stock outstanding immediately after the event.

### ***Events of Default***

The occurrence of any of the following events of default shall, at the option of each investor, make the outstanding principal amount, plus all other amounts payable under such investor's Debenture, immediately due and payable:

our failure to pay the principal amount or any other amount due under the Debenture when due of such failure is not cured within 3 trading days following written notice from an investor;

our breach of any material covenant of the purchase agreement or Debenture in any material respect and the continuation of such breach, if curable, for 10 trading days after written notice of the breach to us from an investor;

if any of our material representations or warranties made in writing in the purchase agreement is untrue in any material respect as of the date of that agreement;

a material default or event of default by us occurs with respect to other material agreements that we are required to file with the SEC in our Annual Report on Form 10-K, other than employment or compensation agreements;

bankruptcy, reorganization, insolvency proceeding, liquidation proceedings or other proceedings for relief under any bankruptcy law is instituted by us or against us and, if instituted against us, is not dismissed within 45 trading days of initiation;

any money judgment, writ or similar final process is entered or filed against us or any of our property or other assets for more than \$250,000 which shall remain unpaid, unvacated, unbonded or unstayed for 45 days;

our default under any mortgage, credit agreement or other facility, indenture, factoring agreement or other instrument under which we issue indebtedness for borrowed money involving an obligation of more than \$150,000 and that results in the acceleration of the indebtedness becoming due or payable;

our common stock becomes ineligible for listing or quotation on a trading market and not eligible to resume listing or quotation within 10 trading days;

we are party to a change of control or fundamental transaction, unless the holders of a majority of the principal amount of Debentures otherwise agree;

if, during the period for which we are required to maintain the effectiveness of the registration statement covering the resale of the Debenture conversion shares, either (i) the effectiveness of such registration statement lapses, (ii) the investors are not permitted to resell their shares for a period of more than 20 consecutive trading days or 30 non-consecutive trading days during any 12-month period, unless we meet the public information requirements under Rule 144 of the Securities Act; or

our failure to deliver our common stock to an investor in accordance with the Debenture within ten trading days after the applicable conversion date

Upon the occurrence of an event of default, each investor shall have the right to require us to pay to such investor a mandatory default amount. The mandatory default amount is equal to the greater of:

the intrinsic value of the common stock underlying the note, which is calculated as (a) the outstanding principal amount of such investor's Debenture divided by (b) the conversion price on the date the mandatory default amount is either demanded or otherwise due, or paid in full, whichever has the lower conversion price, multiplied by the volume-weighted average price of our common stock on the date the mandatory default amount is either demanded or otherwise due, or paid in full, whichever results in the lowest volume-weighted average price, or

115% of the outstanding principal amount of such Debenture,

plus, in each case, all accrued and unpaid interest and all such other amounts, costs, expenses and liquidated damages due in respect of such Debenture.

### *Negative Covenants*

Unless the investors of at least a majority in principal amount of the then outstanding Debentures shall have given prior written consent, as long as any Debentures remain outstanding, we shall not:

incur, create, assume, guarantee or suffer to exist any secured indebtedness for borrowed money other than permitted indebtedness;

enter into, create, incur, assume or suffer to exist any lien of any kind, on or with respect to any of our property or assets now owned or hereinafter acquired other than permitted liens;

repay, repurchase or offer to repay, repurchase or otherwise acquire for cash more than a de minimis number of shares of our common stock other than repurchases of our common stock of departing officers and directors, provided our repurchases shall not exceed an aggregate of \$100,000 during the term of the Debentures;

repay or repurchase or otherwise acquire any indebtedness, other than the Debentures if on a pro-rata basis;

pay cash dividends or distributions on any of our equity securities; or

enter into any transaction with one of our affiliates which would be required to be disclosed in a public filing with the SEC, unless such transaction is at arm's-length and approved by a majority of our disinterested directors.

### **Description of the 2012 Warrants**

*The following description is qualified in its entirety by the terms and conditions of the 2012 Series A Warrants and 2012 Series B Warrants, which we collectively refer to as the 2012 Warrants, the form of which is incorporated by reference as Exhibit 4.7 into the registration statement that contains this prospectus. The following description may not contain all the information with respect to the 2012 Warrants important to you. We encourage you to read the form of 2012 Warrants in its entirety.*

In addition to the Debentures, we issued to the investors 2012 Series A Warrants to purchase, for a period of 5 years from the date of issuance, 49,524,003 shares of our common stock at an initial exercise price of \$0.50 per share, subject to adjustment for stock splits, combinations, recapitalization events. We also issued to the investors 2012 Series B Warrants to purchase, for a period of 18 months from the date of issuance, an additional 49,524,003 shares of common stock at an initial exercise price of \$0.30 per share, subject to adjustment for stock splits, combinations, recapitalization events. The 2012 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.

The applicable exercise prices of the 2012 Warrants Warrant are subject to full ratchet and weighted-average anti-dilution adjustments on the same basis as the Debentures are with respect to Dilutive Issuances. In addition, the exercise price applicable to the 2012 Series B Warrants may be increased to \$0.40, \$0.50 and \$0.75 per share on each of the 6, 12 and 18-month anniversaries, respectively, if the volume weighted average price of our common stock exceeds \$0.30, \$0.50 and \$0.75, respectively, and the daily volume exceeds 100,000 shares during the 10 trading days prior to each applicable anniversary (in each case, subject to adjustment for stock splits, combinations and similar recapitalization events).

The 2012 Series A Warrants may be redeemed by us at a price of \$0.01 per warrant share if, in addition to satisfying each of the equity conditions, for a period of 10 consecutive trading days following the effective date of a registration statement covering the resale of the warrant shares, the volume weighted average price of our common stock is at least \$1.50 and the average daily trading volume of our common stock is at least 100,000 shares on each day during such 10-day period (in each case, subject to adjustment for stock splits, combinations and similar recapitalization events).

## 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 2012 offering incorporated by reference as Exhibit 10.24 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 2012 offering, we entered into a Registration Rights Agreement, dated as of November 26, 2012, with the investors, which we refer to as the Registration Rights Agreement. Pursuant to such agreement, we agreed with the investors to file a registration statement under the Securities Act covering the resale of: (i) 100% of the shares of our common stock issuable as payment of accrued interest under the Debentures and upon exercise of the Series A Warrants; and (ii) 150% of the shares of our common stock issuable upon conversion of the Debentures and upon exercise of the Series B Warrants, and agreed to file the registration statement within 30 days of the November 26, 2012 closing. Such shares of common stock underlying the Debentures and the 2012 Warrants are now being registered pursuant to the registration statement of which this prospectus forms a part.

We have agreed to use our best efforts to have the registration statement declared effective within 60 days after the November 26, 2012 closing date, or 120 calendar days after such closing date in the event the registration statement is subject to review by the SEC. In the event that the total number of shares being registered in the registration statement exceeds the limitations imposed by the Securities and Exchange Commission under Rule 415, we shall reduce the securities to be registered thereunder *pro rata* and, unless otherwise directed in writing by an investor, the number of securities to be registered under the registration statement will first be reduced by any securities that are not “registrable securities,” second by the registrable securities represented by shares of common stock issuable upon conversion of the Debentures and third by the registrable securities represented by shares of common stock issuable upon exercise of the 2012 Warrants.

Registrable securities include:

- 150% of the shares of our common stock issuable upon conversion in full of the Debentures (without regard to any conversion limitations thereunder);

- 100% of the shares of our common stock issuable as payment of accrued interest under the Debentures;

- 100% of the shares of our common stock issuable upon exercise in full of the Series A Warrants (without regard to any conversion limitations thereunder);

150% of the shares of our common stock issuable upon exercise in full of the Series B Warrants (without regard to any conversion limitations thereunder); and

any securities issued or then issuable upon any stock split, dividend or distribution, recapitalization or similar event with respect to the foregoing.

Securities shall cease to be registrable securities when the investors have disposed of all such securities in accordance with an effective registration statement, such securities have been sold in accordance with Rule 144 or such securities become eligible for resale pursuant to Rule 144.

Subject to the terms of the Registration Rights Agreement, upon the occurrence of any non-registration events listed below that incur liquidated damages, we shall pay to each investor an amount in cash, as liquidated damages, equal to 2.0% of the aggregate purchase price paid by such investor for any unregistered registrable securities and for each subsequent 30 day period (prorated for any shorter period) during which such registrable securities are subject to such non-registration event. Non-registration events include:

our failure to file a registration statement on or before the 30<sup>th</sup> business day following the initial closing of the 2012 offering on November 26, 2012;

the registration statement not being declared effective before the 60<sup>th</sup> (or in the case of a full review, the 120<sup>th</sup>) day following the November 26, 2012 closing; or

any registration statement, which previously had been declared effective, ceases to be effective for a period of more than 10 consecutive trading days or more than 15 trading days in any 12-month period.

**SELLING STOCKHOLDERS**

This prospectus covers the resale by the selling stockholders identified below of 208,815,953 shares of our common stock, as follows:

- 60,000 shares that are currently issued and outstanding;
- 74,286,000 shares that are issuable upon the conversion of the Debentures (representing 150% of the shares that are currently issuable upon the conversion of the Debentures, as required pursuant to the Registration Rights Agreement);
- 8,389,948 shares that may be issuable as payment of accrued interest under the Debentures (assumes three years of interest accrual under the Debentures at the rate of 8% per annum, and our election to pay such accrued interest in the form of additional shares of common stock in lieu of cash); and
- 126,080,005 shares that are issuable upon the exercise of outstanding warrants (including 150% of the shares that are currently issuable upon exercise of the Series B Warrants, as required pursuant to the Registration Rights Agreement).

The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of December 24, 2012, and after giving effect to this offering, except as otherwise referenced below.

Selling Stockholder	Shares beneficially owned before offering (1)	Number of shares outstanding offered by selling stockholder	Number of shares offered by selling stockholder upon conversion of debentures	Number of shares offered by selling stockholder (2)	Number of shares issuable in satisfaction of accrued interest offered by selling stockholder	Number of shares offered by selling stockholder upon exercise of warrants	Beneficial ownership after offering (1) Number of shares	Percent
440 Lend LLC (3)	250,000	-	125,000	14,118	208,333	-	-	-
Abel G. Halpern	1,000,000	-	500,000	56,471	833,333	-	-	-
Alan Mendelson (4)	102,124	-	25,000	2,824	41,667	52,124	*	*
Alan T. Yuasa as Trustee of the Michael J. Shimoko Trust (5)	452,095	-	150,000	16,941	250,000	152,095	*	*
Alexander A. Zukiwski (6)	2,091,724	-	750,000	84,706	1,250,000	591,724	*	*
Allan Pantuck and Jodi Pantuck (JTWROS) (7)	68,251	-	25,000	2,824	41,667	18,251	*	*

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Arie and Rebecka Beldegrun as Trustees of the Beldegrun Family Trust dated February 18, 1994 (8)	11,363,359	-	1,750,000	197,647	2,916,667	1,363,358	*
Arie S. Beldegrun M.D. Inc. Profit Sharing Plan (8)	11,363,359	-	1,000,000	112,941	1,666,667	1,363,358	*
Auriga Investors – Montserrat Global Fund (9)(10)	7,500,000	-	3,750,000	423,529	6,250,000	-	-
Benjamin Domb	2,000,000	-	1,000,000	112,941	1,666,667	-	-
Bonnie B. Kazam (11)	657,577	-	125,000	14,118	208,333	157,578	*
Brio Capital Master Fund Ltd. (10)(12)	4,000,000	-	2,000,000	225,882	3,333,333	-	-
Commercial Street Capital LLC (13)	15,891,109	-	6,250,000	705,882	10,416,667	3,391,109	1.4
Gems Progressive Fund II SPC – Perennial S.P. (14)	1,662,788	-	625,000	70,588	1,041,667	412,788	*
Gerald Lieberman	291,277	-	125,000	14,118	208,333	41,277	*
Glenn R. Mattes (15)	1,760,475	-	250,000	28,235	416,667	1,260,475	*
Green Fields Offshore Inc. (16)	2,000,000	-	1,000,000	112,941	1,666,667	-	-
Henry Rothman (17)	327,204	-	150,000	16,941	250,000	27,204	*
Irvin R. Kessler (18)	1,153,037	-	501,000	56,584	835,000	151,037	*
James K. Hu	200,000	-	100,000	11,294	166,667	-	-
Jeffrey E. Donfeld, a Professional Corporation, 401(k) Profit Sharing Plan (19)	1,000,001	-	250,000	28,235	416,667	-	-
Joshua Kazam Trust (20)	270,637	-	125,000	14,118	208,333	20,637	*
Leumi Overseas Trust Corporation Limited as Trustee of the Tampere Trust (8)	11,363,359	-	1,500,000	169,412	2,500,000	1,363,358	*
Marjorie Kaufman and David Kaufman (JTWROS)	2,500,000	-	1,250,000	141,176	2,083,333	-	-
Maxim Partners LLC (21)	2,330,000	60,000	-	-	2,270,000	-	-
MDRB Partnership, L.P. (8)	11,363,359	-	750,000	84,706	1,250,000	1,363,358	*
Ogier Employee Benefit Trustee Limited as Trustee of the MBES Employee Benefit Trust – JD Sub Trust (22)	1,152,095	-	500,000	56,471	833,333	152,095	*



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Selling Stockholder	Shares beneficially owned offering (1)	Number of shares offered by stockholder debentures	Number of shares offered by selling stockholder upon conversion of debentures	Number of shares issuable in satisfaction of accrued interest offered by selling stockholder (2)	Number of shares offered by selling stockholder upon exercise of warrants	Beneficial ownership after offering (1) Number of shares	Percent
Perceptive Life Sciences Master Fund, Ltd. (10)(23)	30,000,000	-	15,000,000	1,694,118	25,000,000	-	-
Peter Kash and Donna Kash (JTWROS) (10)(24)	3,790,606	-	900,000	101,647	1,500,000	1,990,606	*
Pontifax (Cayman) II L.P. (25)	14,582,877	-	2,444,185	276,049	4,073,643	4,582,875	1.9
Pontifax (Israel) II - Individual Investors L.P. (25)	14,582,877	-	714,700	80,719	1,191,168	4,582,875	1.9
Pontifax (Israel) II L.P. (25)	14,582,877	-	1,841,115	207,938	3,068,525	4,582,875	1.9
Primafides (Suisse) SA as Trustees of the Sirius Trust (26)	1,193,901	-	250,000	28,235	416,667	693,901	*
Quantum Partners LP (10)(27)	32,499,999	-	16,250,000	1,835,294	27,083,333	-	-
Rachel Family Partnership LP (28)	304,413	-	125,000	14,118	208,333	54,413	*
RJB Partners LLC (29)	2,000,000	-	1,000,000	112,941	1,666,667	-	-
Sabby Healthcare Volatility Master Fund, Ltd. (10)(30)	12,500,000	-	6,250,000	705,882	10,416,667	-	-
Sabby Volatility Warrant Master Fund, Ltd. (10)(30)	7,500,000	-	3,750,000	423,529	6,250,000	-	-
Stefan Proniuk (31)	369,617	-	100,000	11,294	166,667	169,617	*
The Donfeld Living Trust, dated February 3, 1983, as amended (19)	1,000,001	-	250,000	28,235	416,667	-	-
Uzi Zucker (32)	1,456,287	-	500,000	56,471	833,333	456,287	
Wealthplan Corporation (33)	190,637	-	85,000	9,600	141,667	20,637	*
Wei-Wu He	500,000	-	250,000	28,235	416,667	-	-

TOTAL	60,000	74,286,000	8,389,948	126,080,005
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\* denotes less than 1%

Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange 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 (1) 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. Percentage of shares beneficially owned after the resale of all the shares offered by this prospectus assumes there are outstanding 245,120,895 shares of common stock, including all shares offered hereby that are issuable upon conversion of the Debentures, as payment of accrued interest under the Debentures, or upon exercise of warrants.

Assumes three years of interest accrual under the Debentures at the rate of 8% per annum, and our election to pay (2) such accrued interest in the form of additional shares of common stock in lieu of cash. See “*Description of 2012 Debenture and Warrant Offering.*”

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

(4) In addition to the shares offered hereby, beneficial ownership also includes 50,888 shares of our common stock and 1,236 shares issuable upon the exercise of warrants.

(5) In addition to the shares offered hereby, beneficial ownership also includes 102,095 shares of our common stock and 50,000 shares issuable upon the exercise of warrants.

(6) Dr. Zukiwski is our Vice President, Chief Medical Officer. In addition to the shares offered hereby, beneficial ownership also includes 591,724 shares issuable upon the exercise of options.

(7) In addition to the shares offered hereby, beneficial ownership also includes 12,251 shares of our common stock and 6,000 shares issuable upon the exercise of warrants.

In addition to the shares offered hereby, beneficial ownership also includes: (i) 24,922 shares of our common stock and 516,043 shares issuable upon the exercise of stock options held by Arie Belldegrün, M.D.; (ii) 127,619 shares of our common stock and 62,500 shares issuable upon the exercise of warrants held by Arie and Rebecka Belldegrün as Trustees of the Belldegrün Family Trust dated February 18, 1994; (iii) 317,155 shares of our common stock and 125,000 shares issuable upon the exercise of warrants held by Leumi Overseas Trust (8) Corporation Limited (“Leumi”) as Trustee of the BTL Trust; and (iv) 127,619 shares of our common stock and 62,500 shares issuable upon the exercise of warrants held by MDRB Partnership, L.P. (“MDRB”). Dr. Belldegrün, 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. Richard J. Guillaume and Christopher R.P. Lees, 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.

(9) Dr. Raj Mehra holds voting and/or dispositive power over the shares held by the selling stockholder.

Notwithstanding the number of shares of our common stock shown as beneficially owned by the selling stockholder in the table above, the Debentures and Warrants held by the selling stockholder provide that the (10) selling stockholder may not convert or exercise such Debentures or 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 conversion or exercise.

In addition to the shares offered hereby, beneficial ownership includes: (i) 70,481 shares of our common stock held by Bonnie Kazam; (ii) 20,637 shares of our common stock held by the Joshua Kazam Trust; (iii) 33,230 (11) shares of our common stock held by the Abigail R. Kazam Trust; and (iv) 33,230 shares of our common stock held by the Noah M. Kazam Trust. Ms. Kazam is the trustee of each of the Joshua Kazam Trust, the Abigail R. Kazam Trust, and the Noah M. Kazam Trust.

(12) Shaye Hirsch holds voting and/or dispositive power over the shares held by the selling stockholder. Steven Ruchefsky, President of Commercial Street Capital, LLC, is a director of Arno. In addition to the shares offered hereby, beneficial ownership also includes (i) 2,246,109 shares of our common stock and 1,100,000 (13) shares issuable upon the exercise of warrants held by Commercial Street Capital, LLC, and 45,000 shares of our common stock issuable upon the exercise of options and warrants held by Mr. Ruchefsky.

(14) Cedric Carroll holds voting and/or dispositive power over the shares held by the selling stockholder. Mr. Mattes is our President and Chief Executive Officer and a member of our board of directors. In addition to the (15) shares offered hereby, beneficial ownership also includes 250,000 shares of our common stock and 1,010,475 shares issuable upon the exercise of options.

(16) 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 24,732 shares of our common stock (17) and 2,472 shares issuable upon the exercise of warrants.

(18) In addition to the shares offered hereby, beneficial ownership also includes 148,565 shares of our common stock and 2,472 shares issuable upon the exercise of warrants.

(19) Jeffrey E. Donfeld holds voting and/or dispositive power over the shares held by the selling stockholder. (20) Bonnie Kazam, the trustee of the Joshua Kazam Trust, holds voting and/or dispositive power over the shares held by the selling stockholder.

(21) Michael Rabinowitz holds voting and/or dispositive power over the shares held by the selling stockholder. Tania Bearryman and Donna Laverty, solely in their capacities as authorized signatories of the selling stockholder, hold voting and/or dispositive power over the shares held by the selling stockholder. In addition to (22) the shares offered hereby, beneficial ownership also includes 102,095 shares of our common stock and 50,000 shares issuable upon the exercise of warrants. Ms. Bearryman and Ms. Laverty disclaim beneficial ownership of all securities beneficially owned by the selling stockholder.

(23) 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: (i) 102,095 shares of our common stock and 50,000 shares issuable upon the exercise of warrants held by Dr. and Mrs. Kash (JTWROS); (ii) (24) 1,327,629 shares of our common stock and 152,006 shares issuable upon the exercise of options and warrants held by Dr. Kash; and (iii) 358,876 shares of our common stock held by Mrs. Kash as custodian for the benefit of their minor children under the UGMA.

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) 1,497,248 shares of our common stock and 733,256 shares issuable upon the exercise of warrants (25) held by Pontifax (Cayman) II L.P., (ii) 437,807 shares of our common stock and 214,410 shares issuable upon the exercise of warrants held by Pontifax (Israel) II - Individual Investors L.P., (iii) 1,127,820 shares of our common stock and 552,334 shares issuable upon the exercise of warrants held by Pontifax (Israel) II L.P., and (iv) 20,000 shares of our common stock issuable upon the exercise of options held by Mr. Kariv.

(26) Ari Tatos, Magali Garcia-Baudin, Philip Dean, Philippe De Salis and Bonnie Steiner are directors of Primafides (Suisse) SA, the trustee of the Sirius Trust, and share voting and/or dispositive power over the shares held by the selling stockholder. In addition to the shares offered hereby, beneficial ownership also includes 631,536 shares of our common stock and 62,365 shares issuable upon the exercise of warrants.

(27) Soros Fund Management LLC ("SFM") serves as principal investment manager to the selling stockholder. As such, SFM has been granted investment discretion over portfolio investments, including the shares reported in the table

above, held for the account of the selling stockholder. George Soros serves as Chairman of SFM and Robert Soros serves as President and Deputy Chairman of SFM.

(28) Ruki Renov 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 49,467 shares of our common stock and 4,946 shares issuable upon the exercise of warrants.

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

Each of Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd.

(30) (collectively, the "Sabby Funds") has indicated to us that Hal Mintz has voting and investment power over the shares held by it. Each of the Sabby Funds has also indicated to us that Sabby Management, LLC serves as its investment manager, that Hal Mintz is the manager of Sabby Management, LLC and that each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over these shares except to the extent of any pecuniary interest therein.

(31) Dr. Proniuk is our Vice President of Product Development. In addition to the shares offered hereby, beneficial ownership also includes 169,617 shares issuable upon the exercise of options.

(32) In addition to the shares offered hereby, beneficial ownership also includes 306,287 shares of our common stock and 150,000 shares issuable upon the exercise of warrants.

(33) F. Lawrence Plotnick, president of Wealthplan Corporation, holds voting and/or dispositive power over the shares held by the selling stockholder.

## 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 and assuming the issuance of all shares offered hereby that are issuable upon conversion of the Debentures, as payment of accrued interest under the Debentures, or upon exercise of warrants, there will be 245,120,895 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 owning 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:

- 36,364,942 shares of our common stock,
- options to purchase 5,778,866 shares of our common stock at exercise prices ranging from \$1.00 to \$3.00 per share,
- and
- warrants to purchase 135,269,187 shares of our common stock at exercise prices ranging from \$0.30 to \$2.42 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.

On November 15, 2010, our stockholders, acting by written consent together as a single class, authorized the amendment of our amended and restated certificate of incorporation in order to effect a combination (reverse split) of our common stock at a ratio not to exceed one-for-eight, provided that our board of directors shall have absolute discretion to determine and fix the exact ratio of such combination (not to exceed one-for-eight) and the time at which such combination shall become effective, if ever. As of the date of this prospectus, our board of directors has taken no further action to implement a combination of our common stock and reserves the right to abandon the proposed reverse stock split in its sole discretion.

### **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, all of which are currently designated as Series A Convertible Preferred Stock. Following the conversion of our Series A Preferred Stock into common stock on February 9, 2011, 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 OTC Bulletin Board, or the OTCBB; however, there have been few trades in our common stock since we filed an application to deregister our common stock in May 2009. The

historical trading of our common stock has been extremely limited and sporadic.

Between May 2009 and April 2011, our common stock was eligible for trading on the “Pink Sheets,” where the sole trade was reported on April 9, 2010. Prior to May 2009, our common stock traded on the OTCBB, where the first trade was reported in June 2008. Until July 16, 2008, our common stock traded under the symbol “LRRIOB.” Following our merger with Laurier completed on June 3, 2008, our trading symbol changed to “ARNIOB” on July 17, 2008. Set forth below are the high and low sales prices for our common stock during each quarter within the last two fiscal years, and during each of the first three quarters of fiscal 2012, as reported by the Pink Sheets or the OTCBB, as applicable. 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, 2010	\$-	\$-
June 30, 2010	\$0.51	\$0.51
September 30, 2010	\$-	\$-
December 31, 2010	\$-	\$-
March 31, 2011	\$-	\$-
June 30, 2011	\$-	\$-
September 30, 2011	\$-	\$-
December 31, 2011	\$1.50	\$1.50
March 31, 2012	\$1.25	\$0.60
June 30, 2012	\$1.01	\$0.10
September 30, 2012	\$0.49	\$0.11

## Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of December 24, 2012, we had approximately 250 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 Amended and Restated 2005 Stock Option Plan, which has been approved by our stockholders. The following table sets forth certain information as of December 31, 2011 with respect to our Amended and Restated 2005 Stock Option 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	6,628,555	\$ 1.09	51,601
Equity compensation plans not approved by stockholders:			
None	—	—	—
Total	6,628,555	\$ 1.09	51,601

## 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 a development stage company focused on developing innovative products for the treatment of cancer. The following is a summary of our product development pipeline:

Onapristone – On February 13, 2012, we entered into a license agreement granting us rights to commercially develop onapristone, an anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in breast cancer. Onapristone appears to have a unique ability to block the activated progesterone receptor and inhibit tumor growth. Onapristone was originally developed by Schering AG for potential use as a contraceptive and an anti-endocrine treatment of breast cancer. In clinical studies, onapristone has demonstrated a 56% objective response rate as a first line "hormone" treatment of patients with breast cancer. In connection with the development of onapristone, we intend to develop a companion diagnostic product to identify patients who express the activated form of the progesterone receptor and therefore may be more likely to benefit from treatment with onapristone. We intend to conduct pre-clinical toxicology studies and manufacturing activities and to file an IND or foreign equivalent in 2013.

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. In preclinical studies, AR-42 has demonstrated greater potency and activity in solid tumors and hematological malignancies when compared to vorinostat (also known as SAHA and marketed as Zolinza® by Merck). These data demonstrate the potent and potential differentiating activity of AR-42. Additionally, pre-clinical findings 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, or AML. AR-42 is currently being studied in an investigator-initiated Phase I/II clinical study in adult subjects with relapsed or refractory hematological malignancies: multiple myeloma, chronic lymphocytic leukemia (CLL), or lymphoma. The recommended Phase II dose, or RP2D, in patients with hematological malignancies has been determined and the expansion phase of the program has been initiated. We expect that the expansion phase of the hematological malignancy cohort will take at least 12 months to complete. The protocol has been amended to include a separate solid tumor dose escalation cohort and patients are being actively screened to enter into this cohort. In preclinical studies, AR-42 has demonstrated anti-tumor activity in both meningioma and schwannoma. 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 February 2012, the FDA granted two orphan drug designations for AR-42 for the treatment of meningioma and the treatment of schwannoma of the central nervous system. Additionally, AR-42 has been granted three orphan-drug designations by the European Medicines, 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. We have also applied to the FDA for orphan drug designation of AR-42 for the treatment of NF2 associated central nervous system tumors.

AR-12 – We are also developing AR-12 as an orally available, targeted anti-cancer agent that has been shown in early pre-clinical studies to inhibit phosphoinositide dependent protein kinase-1, or PDK-1, a protein in the PI3K/Akt pathway that is involved in the growth and proliferation of cells, including cancer cells. 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. Preliminary data demonstrates that AR-12 may inhibit multiple different kinase targets. In May 2009, the FDA accepted our IND for AR-12. We are currently conducting a multi-centered Phase I clinical study of AR-12 in adult patients with advanced or recurrent solid tumors or lymphoma. The Phase I study of AR-12 was originally designed to be conducted in two parts. The first part is a dose-escalating study, which we refer to as the Escalation Phase, primarily designed to evaluate the safety of AR-12 in order to identify the MTD and RP2D for future studies of the compound. We anticipate that the Escalation Phase will be completed in the first quarter of 2013. We also anticipate the determination of an RP2D and MTD with the conclusion of the Escalation Phase in the first quarter of 2013. 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 that has been shown to substantially increase bioavailability in preclinical models.

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, a significant amount of our development expenses have related to two of our product candidates: AR-12 and AR-67. As we proceed with the clinical development of our product candidates, primarily focusing our resources on onapristone and AR-42, 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 and warrants. We expense the fair value of stock options and warrants 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**

### ***Three and Nine Months Ended September 30, 2012 Compared to Three and Nine Months Ended September 30, 2011***

*General and Administrative Expenses.* G&A expenses for each of the three months ended September 30, 2012 and 2011 were approximately \$0.5 million, as there were no significant changes from period to period.

G&A expenses for the nine months ended September 30, 2012 and 2011 were approximately \$1.7 million and \$1.4 million, respectively. The increase of approximately \$0.3 million compared to the same period in 2011 is primarily attributable to an increase of approximately \$0.2 million in personnel costs, including stock compensation expense due to having a full-time CEO and executive assistant during the nine months ended September 30, 2012 and no employees in those positions until the second quarter of 2011. There was also an approximately \$0.1 million increase in travel expenses related to general business activities during the nine months ended September 30, 2012 compared to the same period in 2011.

*Research and Development Expenses.* R&D expenses for the three months ended September 30, 2012 and 2011 were approximately \$2.1 million and \$1.4 million, respectively. The increase of approximately \$0.7 million compared to the same period of 2011 is primarily due to our new product candidate, onapristone, which was in-licensed during the first quarter of 2012. Onapristone-related costs for the three months ended September 30, 2012 were approximately \$1.1 million, including approximately \$0.6 million on initial manufacturing activities, approximately \$0.2 million on pre-clinical development activities and approximately \$0.3 million on clinical development support services. This increase of \$1.1 million related to onapristone was partially offset by an approximately \$0.2 million decrease in compensation and consulting costs due to having fewer staff and outside consultants during the third quarter of 2012 compared to the same period in 2011. Additionally, there were decreases of approximately \$0.1 million in each of the AR-12 and AR-67 programs primarily due to reduced nonclinical and regulatory activities.

R&D expenses for the nine months ended September 30, 2012 and 2011 were approximately \$6.3 million and \$4.0 million, respectively. The increase of approximately \$2.3 million compared to the same period in 2011 is primarily due to our new product, onapristone, which was in-licensed during the first quarter of 2012. Onapristone-related costs for the nine months ended September 30, 2012 were approximately \$2.9 million, including a \$0.5 million one-time cash payment to the licensor, approximately \$1.1 million on initial manufacturing activities, approximately \$0.6 million on pre-clinical development activities and approximately \$0.7 million on clinical development support services. Additionally, there was an increase of approximately \$0.3 million relating to AR-42 regulatory efforts that were not being pursued during the same period of 2011. These increases were partially offset by an approximately \$0.8 million decrease in manufacturing and nonclinical activities for AR-12 compared to 2011 resulting from reformulation activities performed during the first nine months of 2011 that were not actively ongoing during the same period in 2012.

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 each of our product candidates for the three and nine months ended September 30, 2012 and 2011, as well as the cumulative amounts since we began development of each product candidate through September 30, 2012. The table also summarizes unallocated costs, which consist of personnel, facilities and other costs not directly allocable to development programs:



	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative amounts during development stage
	2012	2011	2012	2011	
Onapristone	\$ 1,078,145	\$ -	\$ 2,945,930	\$ -	\$ 2,972,348
AR-42	220,241	258,840	813,282	583,396	4,844,759
AR-12	273,993	368,860	779,603	1,538,677	9,622,491
AR-67	81,908	167,701	369,735	373,934	8,034,952
Unallocated R&D	413,570	627,261	1,377,992	1,503,462	9,120,070
Total	\$ 2,067,857	\$ 1,422,662	\$ 6,286,542	\$ 3,999,469	\$ 34,594,620

*Onapristone.* We are currently developing onapristone, an anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in breast cancer. We intend to conduct pre-clinical toxicology studies and manufacturing activities and to file an IND or equivalent in 2013. Based on our current development plans for onapristone, we anticipate spending a total of approximately \$4.7 million on external development costs during the fiscal year 2012, which includes the one-time cash payment of \$0.5 million that we made to Invivis upon execution of the license agreement in February 2012.

*AR-42.* AR-42 is currently being studied in an investigator-initiated Phase I/II clinical study in adult subjects with relapsed or refractory hematological malignancies; multiple myeloma, chronic lymphocytic leukemia (CLL), or lymphoma. The recommended Phase II dose, or RP2D, in patients with hematological malignancies has been determined and the expansion phase of the program has been initiated. We expect that the expansion phase of the hematological malignancy cohort will take at least 12 months to complete. The protocol has been amended to include a separate solid tumor dose escalation cohort, and subjects are being actively screened to enter into this cohort. During 2012, we intend to collaborate with Ohio State to design a Phase 0 investigator-initiated study of AR-42 in patients with surgically resectable schwannoma and meningioma. The primary purpose of this study will be to assess intra-tumoral concentrations of AR-42, identify apoptosis markers and assess gene regulation. Based on our current development plans for AR-42, we anticipate spending a total of approximately \$1.1 million on external development costs during the fiscal year 2012.

*AR-12.* We are also developing AR-12 as a potentially first-in-class, orally available, targeted anti-cancer agent that has been shown in pre-clinical studies to inhibit phosphoinositide dependent protein kinase-1, or PDK-1, a protein in the PI3K/Akt pathway that is involved in the growth and proliferation of cells, including cancer cells. We are currently conducting a multi-centered Phase I clinical study of AR-12 in adult patients with advanced or recurrent solid tumors or lymphoma. The Phase I study of AR-12 is designed to evaluate the safety of AR-12 in order to identify the MTD and RP2D for future studies of the compound. We anticipate the determination of an RP2D and MTD in the first quarter of 2013. Based on our current development plans for AR-12, we anticipate spending a total of approximately \$0.9 million on external development costs during the fiscal year 2012.

Our planned expenditures on our clinical development programs are expected to be substantial, particularly in relation to our available capital resources, and to increase. However, these planned expenditures are subject to many

uncertainties, including 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:

- our ability to obtain additional capital to fund our development programs;
- 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 of manufacturing our drug candidates; and
- the costs, requirements, timing of, and ability to secure regulatory approvals.

*Interest Income.* Interest income for the three and nine months ended September 30, 2012 and 2011 were \$658, \$5,898, \$6,680, and \$24,104 respectively. The decrease in interest income compared to the same periods in 2011 is primarily due to lower average cash balances.

*Other (Expense) Income.* Other expense for the three months ended September 30, 2012 was approximately \$0.4 million compared to other income of approximately \$0.2 million for the same period in 2011. This increase in other expense of approximately \$0.6 million is primarily due to an approximately \$0.4 million noncash adjustment (increase) to the warrant liability during the three months ended September 30, 2012 driven by an increased volatility assumption in the warrant valuation model compared to a decrease of approximately \$0.2 million during the three months ended September 30, 2011.

Other income for the nine months September 30, 2012 was approximately \$2.1 million compared to other expense of approximately \$0.4 million for the same period in 2011. This increase in other income of approximately \$2.5 million is primarily due to approximately \$2.1 million noncash adjustments (decreases) to the warrant liability during the nine months ended September 30, 2012 compared to adjustments (increases to the warrant liability) of approximately \$0.4 million during the nine months ended September 30, 2011. This decrease in the noncash warrant liability is primarily due to the significant decrease in the trading price of the Company's common stock, from \$0.60 to \$0.45, which occurred during the nine months ended September 30, 2012.

***Year Ended December 31, 2011 Compared to Year Ended December 31, 2010***

*General and Administrative Expenses.* G&A expenses for the years ended December 31, 2011 and 2010 were approximately \$2.0 million and \$0.9 million, respectively. This increase of approximately \$1.1 million over 2010 is primarily attributable to an increase of approximately \$0.6 million in personnel costs, including stock compensation expense related to the hiring of a full-time CEO in April 2011 and an executive assistant in June 2011, as no paid employees held those positions during the same period in 2010. Additionally, there is an approximately \$0.2 million increase in legal and accounting fees related to the Company's public filings as a result of becoming a public reporting company during the first quarter of 2011. The Company was not publicly reporting during 2010 and, therefore, did not incur such costs. Additionally, there were increases of approximately \$0.1 million in board fees and travel and entertainment expenses over 2010 due to increased board and management activities compared to 2010.

*Research and Development Expenses.* R&D expenses for the years ended December 31, 2011 and 2010 were approximately \$5.7 million and \$4.1 million, respectively. The increase of approximately \$1.6 million over 2010 is primarily due to an increase of approximately \$0.9 million relating to manufacturing and regulatory activities for AR-42 in 2011 related to potential clinical studies in 2012 and beyond, with no such activities in 2010. Additionally, there was an increase of approximately \$0.6 million in employee compensation costs related to the hiring of a chief medical officer in June 2011 and a clinical operation manager in January 2011, with no employees in such positions during the same period of 2010. There was also an increase of approximately \$0.1 million in costs relating to meetings with scientific advisors and for traveling to various contractor sites in 2011, with minimal amounts of such activities during the same period of 2010. There was also an expense of approximately \$0.1 million in 2011 for certain consultants providing guidance to management regarding the development prioritizations for our licensed compounds with no such expenses during 2010.

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 each of our product candidates for the years ended December 31, 2011 and 2010, as well as the cumulative amounts since we began development of each product candidate through December 31, 2011. The table also summarizes unallocated costs, which consist of personnel, facilities and other costs not directly allocable to development programs:

	Years Ended December 31,		Cumulative
	2011	2010	amounts during
			development
Onapristone	\$26,418	\$-	\$26,418
AR-12	1,860,377	2,037,367	8,842,888
AR-67	554,220	484,279	7,665,217
AR-42	1,035,642	74,653	4,031,477
Unallocated R&D	2,214,179	1,543,255	7,742,078
Total	\$5,690,836	\$4,139,554	\$28,308,078

*Interest Income.* Interest income for the years ended December 31, 2011 and 2010 was \$28,771 and \$19,339. The increase in interest income over 2010 is due to higher average cash balances levels as a result of our September 2010 private placement.

*Other Income (Expense).* For the year ended December 31, 2011, we had other expense of approximately \$0.3 million, most of which related to noncash adjustments to the warrant liability with no such charges in 2010. For the year ended December 31, 2010, we had other income of approximately \$1.0 million which consisted primarily of the approximately \$0.7 million in funding received under the IRS Qualifying Therapeutic Discovery Project for our product candidates and proceeds from our sale of approximately \$4.0 million of New Jersey net operating losses pursuant to our participation in the New Jersey Tax Benefit Transfer Program.

### Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2012 and December 31, 2011 and our net changes in cash and cash equivalents for the nine months ended September 30, 2012 and 2011 (the amounts stated are expressed in thousands):

Liquidity and capital resources	September 30, 2012	December 31, 2011
Cash and cash equivalents	\$ 594	\$ 6,678
Working Capital	\$ (2,371	) \$ 5,012
Stockholders' (deficit) equity	\$ (3,931	) \$ 1,356

  

Cash flow data	Nine Months Ended September 30,	
	2012	2011
Cash used in:		
Operating activities	\$ (6,085	) \$ (4,994
Investing activities	-	(9
Net decrease in cash and cash equivalents	\$ (6,085	) \$ (5,003

Our total cash resources as of September 30, 2012 were approximately \$0.6 million compared to approximately \$6.7 million as of December 31, 2011. As of September 30, 2012, we had approximately \$4.9 million in liabilities (of which approximately \$1.6 million represented a non-cash warrant liability), and negative working capital of approximately \$2.4 million. We incurred a net loss of approximately \$5.9 million and had negative cash flow from operating activities of \$6.1 million for the nine months ended September 30, 2012. Since August 1, 2005 (inception) through September 30, 2012, we have incurred an aggregate net loss of approximately \$41.4 million, while negative cash flow from operating activities has amounted to \$34.8 million. As we continue to develop our product candidates, we expect to continue 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 the conducting of pre-clinical studies and clinical trials.

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 may 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, and taking into account the net proceeds from our 2012 offering of Debentures and Warrants, we believe we have cash on hand to fund our operations through approximately the third quarter of 2013. However, based on the various options for future clinical studies of onapristone, AR-42 and AR-12, 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 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 of our research activities;
  
- the costs of hiring additional full-time personnel;

- the number and scope of our research programs;
- the progress 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.

### **Off -Balance Sheet Arrangements**

There were no off-balance sheet arrangements as of December 31, 2011 or September 30, 2012.

### **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.

During the period in which our common stock was registered under the Securities Exchange Act and publicly traded (October 3, 2008 through May 5, 2009), our management used the following assumptions: On the option grant date, the current available quoted market price for determining the fair value of our common stock, an expected volatility based on the average expected volatilities of a sampling of five companies with similar attributes to us, including industry, stage of life cycle, size and financial leverage, an expected dividend rate of 0% based on management plan of operations, a risk free interest rate based on the current U.S. Treasury 5-year Treasury Bill and an expected forfeiture rate of 0%.

Subsequent to the deregistration of our common stock in May 2009, for all options granted in 2009, management estimated the fair value of our common stock to be \$1.00 based on the following factors. The stock was publicly trading at \$1.00 per share prior to being deregistered. Subsequent to the deregistration, we did not experience any significant events including clinical trial results, new product acquisitions or discoveries which management believes would influence a material change in share price following the deregistration. In addition, our management used the following assumptions for options granted during this period: An expected volatility based on the average expected volatilities of a sampling of five companies with similar attributes to us, including industry, stage of life cycle, size and financial leverage, an expected dividend rate of 0% based on management plan of operations, a risk free interest rate based on the current U.S. Treasury 5-year Treasury Bill and an expected forfeiture rate of 0%.

On February 9, 2011, the effective date of the registration statement filed in connection with our September 2010 private placement of Series A Preferred Stock, we again became subject to the reporting requirements of the Exchange Act. Due to the lack of an active public market for our common stock, management estimated the fair value of our common stock using a Monte Carlo simulation model and, in doing so, 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 our future expected stock prices and minimizes standard error. Management used this valuation for options granted in 2011 (no stock options were granted during the nine months ended September 30, 2012). In addition, our management used the following assumptions for options granted during this period: An expected volatility based on the average expected volatilities of a sampling of five companies with similar attributes to us, including industry, stage of life cycle, size and financial leverage, an expected dividend rate of 0% based on management plan of operations, a risk free interest rate based on the current U.S. Treasury 5-year Treasury Bill and an expected forfeiture rate of 0%.

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.

## OUR BUSINESS

### Overview

We are a development stage company focused on developing innovative products for the treatment of cancer. The following table summarizes our product development pipeline:

<b>Product</b>	<b>Indications</b>	<b>Commercial</b>	<b>Ongoing Studies / Status</b>
<b>Candidate</b>		<b>Rights</b>	
Onapristone	Breast and endometrial cancer	Arno	Manufacture of drug substance and drug product is currently underway. Pre-clinical toxicology will be initiated upon availability of drug substance. Work is ongoing on a companion diagnostic intended to enhance selection of patients most likely to benefit from treatment with onapristone.
AR-42	Hematological malignancies	Arno	An investigator-initiated Phase I/IIa clinical study of AR-42 is ongoing at The James Cancer Center at The Ohio State University in patients with advanced or recurrent hematological malignancies and solid tumors for which standard treatment has failed or not proven to be effective.
AR-12	Solid tumors and hematological malignancies	Arno	A two part, multi-centered Phase I clinical trial of AR-12 is ongoing in patients with solid tumors and lymphoma who have progressed despite treatment with other therapies.

### 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 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.

## 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 2012. According to a 2012 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 2007 were \$103.8 billion. With a 67% 5-year relative survival rate for all cancers from 2001-2007, 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 (other than in France) commercialize onapristone, an anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in breast cancer. Onapristone appears to have a unique ability to block the activated progesterone receptor, which is believed to be the mechanism by which it may inhibit the growth of breast and endometrial tumors. Onapristone was originally being developed by Schering AG for potential use as a contraceptive and an anti-endocrine treatment of breast cancer. In 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 to identify patients who express the activated form of the progesterone receptor and therefore may have an enhanced likelihood to benefit from treatment with onapristone. During 2012, we intend to conduct pre-clinical toxicology studies and manufacturing activities that will enable us to file an investigational new drug application, or IND, with the U.S. Food and Drug Administration, or the FDA, in 2013.

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 believed to play important roles in the development of certain female cancers (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. Breast and endometrial cancers commonly express estrogen and progesterone receptors, but to date we have not identified if these receptors are functional and playing a role in tumor growth. A better diagnostic test may aide in selecting patients who are most likely to benefit from “hormone” treatment including onapristone.

Onapristone is a type 1 anti-progestin. Its mechanism of action is thought 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 or differentiation of the malignant cell.

#### *Potential Advantages*

In prior clinical studies, onapristone had 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 with tamoxifen resistant disease. Clinical studies of onapristone are intended to evaluate safety and efficacy which may provide women with breast and endometrial cancer an additional treatment option and allow a delay in the time for which patients may need chemotherapy treatment.

#### *Development Plans and Activities*

We recently completed a series of preclinical studies of onapristone. In these studies, 10 different breast cancer and endometrial cancer cell lines were 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 24<sup>th</sup> European Organization for Research and Treatment of Cancer symposium on Molecular Targets and Cancer Therapeutics in Dublin, Ireland.

In addition, as stated above, a key aspect of our strategy to develop onapristone is to also develop a companion diagnostic that would identify patients who express APR and therefore would be more likely to respond to treatment with onapristone. We and our research collaborators recently identified a new immunohistochemistry technique for identifying activated progesterone receptors in breast cancer tumors, the findings of which we presented in December 2012 at the 35<sup>th</sup> Annual San Antonio Breast Cancer Symposium. This 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 paraffin-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 technique in other malignancies.

We need to complete additional animal toxicology studies on onapristone before we will be in position to begin evaluating onapristone in human subjects. Following completion of the planned preclinical studies and our development of companion diagnostic, we intend to file an IND with the FDA seeking to commence a dose escalation Phase I study of onapristone in patients with endometrial and breast cancers.

## **AR-42**

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<sup>®</sup>), the first of only two 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 Phase I/IIa trial of AR-42 in patients with hematological malignancies and solid tumors is ongoing at Ohio State.

### *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<sup>®</sup>, Celgene Corporation) is approved to treat CTCL and peripheral T-cell lymphoma. These two 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 is conducting an investigator-initiated Phase I/IIa study of AR-42 in patients with advanced or recurrent hematological malignancies for which no treatment is available. 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 has been declared and we expect to identify the recommended dose for further study for patients with solid tumors by the first quarter of 2013.

The ongoing study is designed so that additional patients with hematological malignancies can be added to investigate the efficacy of AR-42 in a particular disease and help guide future Phase II programs once the recommended dose for further study has been defined. Up to an additional 10 patients may be enrolled at the recommended phase 2 dose in each of the following disease cohorts: CLL/small lymphocytic lymphoma, multiple myeloma, and lymphoma. We expect this expansion phase will take at least 12 months to complete.

In addition, 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. During 2012, we intend to collaborate with Ohio State to conduct a Phase 0 investigator-initiated study of AR-42 in patients with schwannoma and meningioma. The primary purpose of this study will be to assess intra-tumoral concentrations of AR-42, identify apoptosis markers and assess gene regulation.



## **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 is currently enrolling patients in a Phase I clinical study. AR-12 has been shown in pre-clinical studies to inhibit phosphoinositide dependent protein kinase-1, or PDK-1, that targets the Akt pathway, while also possessing activity in the endoplasmic reticulum stress pathway and other pathways targeting apoptosis. 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. We are currently enrolling patients with advanced or recurrent solid tumors or lymphoma in a Phase I clinical study of AR-12.

### *Mechanism of Action*

AR-12 has been shown in pre-clinical studies to inhibit a protein known as PDK-1, 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. 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 inhibitors of PI3K, PDK-1, and Akt.

PDK-1 can transform normal human cells and may be involved in the invasion and metastasis process. PDK-1 and its downstream target, the protein Akt, are frequently activated in multiple cancer types, and inhibiting PDK-1 facilitates the dephosphorylation and subsequent inactivation of Akt. Activation of the PDK-1/Akt pathway confers resistance to cell death signaling and the apoptotic activity of other cytotoxic agents. Additionally, recent research has

demonstrated the importance of PDK-1 in oncology that is independent of its Akt modulation. The inhibition of the PDK-1/Akt pathway in cancer cells where this pathway was previously active has been shown to decrease cell proliferation and increase programmed cell death, which is known as apoptosis. Preclinical data suggests that AR-12 inhibits PDK-1 and data collected from preclinical toxicology studies and tumor distribution studies indicate that AR-12 would be expected to exceed therapeutic concentrations *in vivo*.

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.

#### *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.

We believe AR-12 is a potentially first-in-class molecule in human clinical development. We also believe that PDK-1 may prove to be highly desirable target for oncology; therapeutic strategies to modulate the Akt pathway are of great scientific, clinical, and financial interest, and there are a few molecules in development that seek to target Akt through the inhibition of a protein known as PI3K. PDK-1 is downstream of PI3K and thus may be more likely to impact the desired molecular targets further downstream and less likely to result in off-target toxicity. Inhibition of PDK-1 also seems to be able to regulate other important oncology targets that are not be mediated by PI3K. In addition to targeting PDK-1, we believe that AR-12 also has the ability to induce ER stress and has the potential to become an important agent in a range of cancer indications.

#### *Clinical Development*

We are currently enrolling subjects 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 is being 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 is a dose-escalating study, which we refer to as the Escalation Phase, that is 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 include 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 also anticipate the determination of a RP2D or MTD with the conclusion of the Escalation Phase in the first quarter of 2013. 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.

The biomarker selection and evaluation is being led by Johann de Bono, M.D., Ph.D. of The Royal Marsden Hospital in London. Dr. de Bono is a prominent researcher in oncology drug development and has been involved in the successful development of novel targeted therapies.

We believe that the data generated from the current Phase I study will provide important information to direct future studies, in terms of safety, pharmacokinetics and potential efficacy. We also believe that the biomarkers and pharmacodynamic assays planned for 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 information generated in these studies will also help to guide the potential future development of AR-12.

## **Competition**

We compete primarily in the cancer therapeutic segment of the biopharmaceutical market that addresses cancer therapeutics, 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 above under "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) used in the treatment of breast and endometrial 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.

Although onapristone has a known risk for elevated liver function tests, we believe that 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.

## ***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”). Additionally, in November 2009 Gloucester Pharmaceuticals received FDA approval for its novel HDAC inhibitor, romidepsin, to treat CTCL before being acquired by Celgene Corp. in December 2009. Subsequently, romidepsin (Istodax®, Celgene Corporation) has been approved for the treatment of patients with peripheral T-cell lymphoma. Other HDAC inhibitors are in Phase II and Phase III 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.

## ***AR-12***

AR-12 is believed to target PDK-1, which is in the PI3K/Akt pathway. Targeting the PI3K/Akt pathway 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 PDK-1 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.

## **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 provides us with exclusive, worldwide rights to a U.S. provisional 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. We will make the first milestone payment to Invivis upon the dosing of the first subject in the first Company-sponsored Phase I clinical trial of onapristone, which is not anticipated until 2013. 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, Invivis will provide us 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.

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.

#### ***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 one issued U.S. patent and four pending U.S. patent applications that relate to AR-12 and particular uses of AR-12 according to our business plan. The issued patent includes composition of matter claims. The issued patent is 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 2028.

Under our license agreement for AR-42, we have exclusive, worldwide rights to two pending U.S. patent applications that relate to AR-42 and particular uses of AR-42 according to our business plan. If either or both of the pending patent applications issue, the issued patent or patents would both be scheduled to expire in 2024. In addition, in 2010, we filed one U.S. provisional patent application directed primarily to particular methods of using AR-42. If any U.S.



patent claiming priority to the provisional patent applications issues, such a patent would be scheduled to expire in 2031.

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. The first milestone payment for AR-42 will be due when the first patient is dosed in the first Company-sponsored Phase I clinical trial. 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 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.

### ***AR-67 License Agreement***

We formerly held exclusive rights to develop and commercialize an oncology therapeutic drug candidate known as AR-67 pursuant to an October 2006 license agreement with the University of Pittsburgh ("Pitt"). Under this agreement, Pitt granted us an exclusive, worldwide, royalty-bearing license for the rights to commercialize technologies embodied by certain issued patents, patent applications and know-how relating to AR-67 for all therapeutic uses. In 2006, pursuant to the license agreement, we made a one-time cash payment of \$350,000 to Pitt and reimbursed it for past patent expenses. Additionally, Pitt was also entitled to receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to AR-67. We would have made the first milestone payment to Pitt upon the acceptance of the first new drug application by the FDA for AR-67. We were also required to pay to Pitt an annual maintenance fee of \$200,000 upon the third and fourth anniversaries, \$250,000 upon the fifth and sixth anniversaries, and \$350,000 upon the seventh anniversary and annually thereafter and to pay Pitt a royalty equal to a percentage of net sales of AR-67, pursuant to the license agreement.

Under the license agreement with Pitt, we also agreed to indemnify and hold Pitt and its affiliates harmless from any and all claims, actions, demands, judgments, losses, costs, expenses, damages and liabilities (including reasonable attorneys' fees) arising out of or in connection with (i) the production, manufacture, sale, use, lease, consumption or advertisement of AR-67, (ii) the practice by us or any affiliate or sublicensee of the licensed patent; or (iii) any obligation of us under the license agreement unless any such claim is determined to have arisen out of the gross negligence, recklessness or willful misconduct of Pitt.

On January 12, 2012, we received a notice from Pitt, indicating that we were in default under the license agreement for failure to pay a \$250,000 annual license fee under the terms of that agreement and providing us with 60 days' notice to remedy the default. On March 29, 2012, following our determination not to proceed with further development of AR-67, we agreed with Pitt to terminate the license agreement. As of September 30, 2012, we have accrued for the outstanding annual license fee of \$250,000, while we are working to wind down our AR-67 program.

## **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, on occasion, in patients, such as cancer patients. 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 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. 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 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.

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 \$5.7 million in fiscal year 2011 and \$4.1 million in fiscal year 2010 on research and development activities. For the nine months ended September 30, 2012, we spent approximately \$6.3 million 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 December 31, 2011, we had six full-time employees, none of whom are covered by a collective bargaining agreement. During January 2012, our Chief Operations Officer and Senior Clinical Study Manager resigned their employment with us. We believe our relations with our employees are satisfactory.

We utilize clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, and manufacturing. We are currently engaged in an active search for additional research and development staff, as required, to support our product development.

## **Legal Proceedings**

We are not involved in any pending legal proceedings. In January 2012, we received a notice from the University of Pittsburgh, or Pitt, claiming that we were in default under our license agreement relating to AR-67 for failure to pay a \$250,000 annual license fee under the terms of that agreement and providing us with 60 days' notice to remedy the default. On March 29, 2012, following our determination not to proceed with further development of AR-67, we agreed with Pitt to terminate the license agreement. In September 2012, we received a Praecipe to Issue a Writ of Summons from Pitt, but as of the date of this prospectus we have not been served with a summons or complaint or otherwise had further communication with Pitt with respect to this matter.

## **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 a lease agreement dated August 4, 2011. 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. 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.	63	Chairman of the Board
Glenn Mattes	57	President, Chief Executive Officer and Director
Alexander Zukiwski, M.D.	55	Vice President, Chief Medical Officer
David M. Tanen	41	Secretary and Director
Scott L. Navins	41	Treasurer
Stefan Proniuk, Ph.D.	42	Vice President of Product Development
William F. Hamilton, Ph.D.	73	Director
Tomer Kariv	51	Director
Yacov Reizman	61	Director
Steven B. Ruchefsky	50	Director

*Arie S. Belldegrun, M.D., FACS* has served as the chairman of Arno's board of directors since March 2008. He is currently the Chairman of Two River Group Management, LLC, the managing member of Two River Group Holdings, LLC, and the chairman of the managing member of Two River Consulting, LLC, an organization that provides management, consulting and operational services for development stage biotechnology companies, including Arno. See "Certain Relationships and Related Party Transactions." Dr. Belldegrun is Professor and Chief of Urologic Oncology at the David Geffen School of Medicine at the University of California, Los Angeles, where he holds the Carol and Roy Doumani Chair in Urologic Oncology. He received his medical degree at the Hebrew University Hadassah Medical School, and conducted his post-doctoral studies at the Weizmann Institute of Science in Israel. He completed his Urologic Surgery residency at Harvard Medical School in 1985 and his Surgical Oncology fellowship at the National Cancer Institute/National Institute of Health in 1988. 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 also the founder and founding chairman of Agensys Inc., a privately held biotechnology company developing fully human antibody cancer therapeutics based on novel and clinically relevant targets. In December 2007, Agensys was acquired by Astellas Pharma, Inc. in a deal valued at \$537 million. Dr. Belldegrun served as Vice-Chairman of the Board of Directors and Chairman of the Scientific Advisory Board of Cougar Biotechnology, an oncology-focused biopharmaceutical company, until its sale to Johnson & Johnson in July 2009. Since October 2009, Dr. Belldegrun has served as a director of Nile Therapeutics, Inc., a publicly-held company focused on the development of biopharmaceutical products for the treatment of cardiovascular diseases. He is also the Chairman of the Board of Directors of Kite Pharma, Inc., a privately held company focused on the development of immune-based targeted therapies to treat different cancer indications. Dr. Belldegrun is on the scientific boards of several biotechnology and pharmaceutical companies and is a reviewer for many medical journals and granting organizations. He served as Chairman of the Molecular and Biological Technology Committee of the American Urological

Association and member of its Technology Assessment Council, as a member of the Governor's council on Bioscience for the State of California, and as a biotechnology group leader and member of The Los Angeles Economy and Jobs Committee established in October 2006 by Mayor Antonio Villaraigosa. He is the author of several books on prostate and kidney cancers, holds several biopharmaceutical patents, and has written over 400 scientific publications with an emphasis on urologic oncology.

**Glenn Mattes** was appointed to serve as Arno's President, Chief Executive Officer, and director in April 2011. He has over 25 years of commercialization and general management experience across a wide range of businesses. From 2002 to 2011, Mr. Mattes served as the President of Tibotec Therapeutics, a Johnson & Johnson operating company focused on oncology and virology therapeutics, where he led the organization responsible for the development, marketing and sales of novel antiretroviral compounds in North America. Under Mr. Mattes' leadership, Tibotec successfully launched the first two Johnson & Johnson products in the United States' HIV/AIDS market. In 2008, Mr. Mattes was appointed to the President's Advisory Council on HIV/AIDS (PACHA) by the U.S. Secretary of Health and Human Services to counsel White House administrations on both domestic and global health and treatment issues. Prior to Tibotec, from 1998 to 2002 Mr. Mattes served as the Vice President of Worldwide Commercial Operations at Centocor, where he played a critical role in defining Centocor's overall business direction, as well as developing and implementing the organization's sales and marketing strategy leading to the introduction of Remicade®. Prior to joining Centocor, Mr. Mattes gained a wealth of pharmaceutical experience at Rhone Poulenc Rorer (RPR) (now Aventis), where he held positions of increasing responsibility, including President of RPR Canada, and Vice President of Advanced Therapeutics and Oncology, North America, where he was largely responsible for the successful launch of both Taxotere® and Lovenox®. Mr. Mattes received a BS degree from the City University of New York.

**Alexander Zukiwski, M.D.**, was appointed to serve as Arno's Vice President and Chief Medical Officer in June 2011. 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. In September 2004, Mr. Tanen co-founded Two River Group Holdings, LLC ("Two River"), a venture capital firm that specializes in the creation of new companies that acquire rights to commercially develop biotechnology products, and currently serves as Vice President and Director of Two River's managing member, Two River Group Management, LLC. 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 "Certain Relationships and Related Party Transactions." 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.

**Scott L. Navins** has served as Arno's Treasurer since its inception, and has been responsible for all of our accounting and financial reporting services since the departure of our former Chief Financial Officer in February 2010. He is also the Vice President of Finance at Two River Group Holdings, LLC ("Two River") and Two River Consulting, LLC, where he is responsible for all accounting, finance and control activities. Mr. Navins joined Two River in 2005. Prior to joining Two River, from 2004 to 2005 Mr. Navins was the Senior Controller at Westbrook Partners, where he managed the accounting for a \$560 million real estate private equity fund, including financial and partner reporting, tax coordination, maintaining internal controls and overseeing a \$300 million credit facility, among other things. Before that, from 2002 to 2004 Mr. Navins was a Senior Manager at Morgan Stanley, where he managed the accounting for a \$2.4 billion real estate private equity fund. Prior to that Mr. Navins was an Associate in the Finance Group at BlackRock, Inc. and the controller for a high-tech venture capital fund. Mr. Navins also serves as the Financial and Operations Principal of Riverbank Capital Securities (member FINRA/SIPC) and has served as Treasurer of Nile Therapeutics, Inc., a publicly-held biopharmaceutical company, since 2005. Mr. Navins graduated with honors from The George Washington University in 1993, where he earned a Bachelor of Accountancy degree. Mr. Navins passed the Uniform Certified Public Accounting examination in 1993.

**Stefan Proniuk, Ph.D.** has over 12 years of experience in formulation and product development. Prior to joining Arno, he was the Sr. Manager of Pharmaceutical Technologies at Neurocrine Biosciences (2002-2008) where he was responsible for overseeing development programs from Phase I to III. His group was also responsible for the preformulation of NCEs. Prior to his work at Neurocrine, Dr. Proniuk worked as a scientist at Cima Labs (2001-2002) on the development and scale-up of fast dissolving tablet formulations (OraSolv<sup>®</sup>, DuraSolv<sup>®</sup>). Throughout his career he has worked on 2 NDAs, 8 INDs, 1 IMPD, 1 CTA, and 3 marketed products. Dr. Proniuk holds a Ph.D. degree in Pharmaceutical Sciences from the University of Arizona, a MBA with emphasis in Entrepreneurship from San Diego State University and a Diplom (FH) in Chemical Engineering from the Polytechnical University Isny in Germany. He is also certified in Intellectual Property Law from the University of California San Diego.

**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 serves on the board of directors of Ceptaris Therapeutics, Inc., a privately-held specialty pharmaceutical company that develops small molecule pharmaceuticals licensed from academic laboratories. 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** 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 is a board member of Macrocare 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.

**Yacov Reizman** 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** is President of Commercial Street Capital LLC, a private investment company and significant stockholder in Arno. For the last decade, Mr. Ruchefsky has been working as an investment manager for the founder and CEO of a multi-billion dollar hedge fund. Mr. Ruchefsky began his career at a prominent New York City law firm where he became a partner, member of management and chair of a specialized litigation group. Upon leaving his law firm and prior to his current employment, Mr. Ruchefsky was a principal of an early stage venture capital operation. In addition to Arno, Mr. Ruchefsky currently sits on the boards of several public and private companies, including Itamar Medical (TASE: ITMR), Kite Pharma, Inc, MD Solar Sciences, Inc. 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 an early-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, Reizman, Ruchefsky and Tanen have venture capital or investment banking backgrounds and offer expertise in financing and growing small companies, particularly small biopharma and life science companies. Each of Drs. Beldegrun and Hamilton and Mr. 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. Beldegrun'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. Mr. Mattes' extensive commercialization and general management experience and his current position as our President and Chief Executive 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, Reizman, Ruchefsky and Dr. Hamilton are "independent" within the meaning of the applicable listing standard of the NASDAQ Stock Market. Messrs. Mattes, Tanen and Dr. Beldegrun are not independent, as defined by applicable NASDAQ listing standards.

## **Executive Compensation**

The following table sets forth all of the compensation for the 2011 and 2010 fiscal years awarded to, earned by or paid to (i) all individuals serving as our principal executive officer during the fiscal year ended December 31, 2011; and (ii) two other individuals that served as an executive officer at the conclusion of the fiscal year ended December 31, 2011 and who received in excess of \$100,000 in total compensation during such fiscal year. We refer to these individuals as our named executives.

## **Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (1) (\$)	Option Awards (1) (\$)	All Other Compensation (2) (\$)	Total (\$)
Glenn R. Mattes (3) President and CEO	2011	68,590	120,342	172,750	1,098,200	12,750	1,472,632
Alexander Zukiwski, M.D. (4) VP and Chief Medical Officer	2011	197,596	100,000	—	854,000	6,500	1,158,096
David M. Tanen (5) Former President	2011 2010	— —	— —	— —	— —	— —	— —
J. Chris Houchins (6) Former Chief Operating Officer	2011 2010	225,000 209,756	— 102,422	— —	256,200 —	— —	481,200 312,178

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

(2) Amounts represent automobile allowances.

(3) Mr. Mattes was appointed President and Chief Executive Officer on April 25, 2011.

(4) Dr. Zukiwski was appointed Vice President, Chief Medical Officer on June 22, 2011.

Mr. Tanen served as Arno's President from June 8, 2009 until the appointment of Mr. Mattes as President and Chief Executive Officer on April 25, 2011. Mr. Tanen, who also serves as a director, did not receive compensation for his service as President. However, Two River Consulting, LLC did receive compensation for Mr. Tanen's services as President of Arno. See "Certain Relationships and Related Transactions, and Director Independence." (5) Mr. Tanen also receives compensation for his service as a director in accordance with the terms of our non-employee director compensation plan. See "—Director Compensation."

(6) Mr. Houchins resigned his employment with us, effective as of January 13, 2012.

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

*Glenn Mattes*

*President and Chief Executive Officer*

Mr. Mattes' employment with us is governed by an employment agreement dated April 25, 2011. The agreement provides for a three-year term expiring on April 25, 2014, 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, Mr. Mattes will receive an initial annualized base salary of \$100,000 for a period of one year, after which his base salary will be increased to \$350,000 per year, subject to further increases on an annual basis in accordance with the consumer price index plus 1%. The employment agreement further provides that, subject to the successful achievement of specific performance objectives to be established by the Board, Mr. Mattes will be eligible to receive an annual performance bonus of up to 50% of his annualized base salary; provided, however, that Mr. Mattes will be eligible to receive a performance bonus of up to \$175,000 during the first year of the term. For 2011, our Board of Directors awarded Mr. Mattes a performance bonus of \$120,342, representing 100% of his target bonus prorated for his service during the year. In the event of a "Change of Control" (as defined in the Company's 2005 Stock Option Plan), Mr. Mattes shall receive a cash bonus in an amount equal to the greater of (a) \$100,000, and (b) 0.15% of the amount by which the aggregate consideration to be received by Arno and/or our stockholders in connection with such Change of Control exceeds \$100,000,000.

Pursuant to the employment agreement, on the date of the agreement, Mr. Mattes was granted 10-year options to purchase a total of 2,354,379 shares of our common stock at an exercise price equal to \$1.00 per share. Options relating to 60% of such shares are designated as "Employment Options" and options relating to the remaining 40% of the shares are designated as "Performance Options." The right to purchase 25% of the shares subject to the Employment Options will vest and become exercisable on April 25, 2012, and thereafter the remaining shares subject to the Employment Options will vest and become exercisable in 24 equal monthly installments. The right to purchase the shares subject to the Performance Options shall 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, Mr. Mattes' Performance Options would vest in the maximum potential amount of 215,872 shares. In addition, Mr. Mattes was granted 250,000 shares of our common stock (the "Restricted Shares") on the date of the employment agreement. The Restricted Shares shall vest in 12 equal monthly installments beginning on May 25, 2011.

The employment agreement provides that if Arno terminates Mr. Mattes without "Cause," or if he resigns for "Good Reason" (each as defined in the 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; (iii) an acceleration in the vesting of the Employment Options and Restricted Shares such that all unvested Employment Options and Restricted Shares shall be deemed vested as if Mr. Mattes had remained continuously employed with Arno for one year

following his termination date; and (iv) the vesting of all earned but unvested Performance Options. In addition to the foregoing, in the event that Mr. Mattes' employment is terminated in connection with a Change in Control, then Mr. Mattes shall also be entitled to the immediate vesting of all unvested Employment Options, Performance Options, and Restricted Shares.

*Alexander Zukiwski, M.D.*

*Vice President and Chief Medical Officer*

Dr. Zukiwski's employment with us is governed by an employment agreement dated June 22, 2011. The agreement provides for a three-year term expiring on June 22, 2014, 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. 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 2011, our Board awarded Dr. Zukiwski a performance bonus of \$100,000, representing approximately 100% of his target bonus, prorated for his service during the year. Pursuant to the employment agreement, we have 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 1,750,000 shares of our common stock at an exercise price equal to \$1.00 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 will vest and become exercisable on June 22, 2012, and thereafter the remaining shares subject to the Employment Options will vest and become exercisable in 24 equal monthly installments. The right to purchase the shares subject to the Performance Options shall 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 154,224 shares.

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.

***J. Chris Houchins***

***Former Chief Operating Officer***

Mr. Houchins’ employment with us was governed by a letter agreement dated September 12, 2007, as amended on August 26, 2010. Under the letter agreement, which provided for Mr. Houchins’ employment with us on an at-will basis, Mr. Houchins was entitled to an annual base salary of 180,000, which was subsequently increased to 207,500 on January 1, 2009 and to \$225,000 on November 16, 2010. In addition, Mr. Houchins was eligible to receive an annual performance bonus of up to 25% of his base salary upon the successful completion of annual corporate and individual milestones. The letter agreement also provided for the awarding of certain stock options to Mr. Houchins, referred to as Employment Options. On September 17, 2007, Mr. Houchins was granted ten-year Employment Options to purchase 99,689 shares of our common stock at an exercise price of \$1.00, with one-quarter vesting after one year and the remainder vesting in 36 equal monthly installments thereafter. On September 29, 2009, Mr. Houchins was granted ten-year Employment Options to purchase 200,000 shares of our common stock at an exercise price of \$1.00, vesting in three equal annual installments commencing on the first anniversary of the grant date. In addition, on June 20, 2011, Mr. Houchins was granted 10-year options to purchase a total of 525,000 shares of our common stock at an exercise price equal to \$1.00 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 25% of the shares subject to the Employment Options vested immediately and, of the remaining shares, 25% were scheduled to vest 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 scheduled to vest, if at all, in three equal annual installments, subject to the successful achievement of specific performance objectives to be established by the Board. As a result of Mr. Houchins’ resignation, which was effective January 13, 2012, all future vesting under his options was forfeited. To the extent vested, Mr. Houchins’ options remained exercisable for a 90-day or three-month period following his resignation, after which the options terminated.

**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, 2011:

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Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price (\$)	Option Expiration Date	
Mr. Tanen	10,000	-	1.00	9/29/19	(1)
	3,333	6,667	1.00	11/5/20	(2)
Mr. Houchins (3)	99,689	-	1.00	9/17/17	(4)
	133,333	66,667	1.00	9/29/19	(5)
	52,500	236,250	1.00	6/20/21	(6)
	-	236,250	1.00	6/20/21	(7)
Mr. Mattes	215,872	725,880	1.00	4/25/21	(8)
	-	1,412,627	1.00	4/25/21	(9)
Dr. Zukiwski	154,224	720,776	1.00	6/22/21	(10)
	-	875,000	1.00	6/22/21	(11)

(1) Option granted on September 29, 2009, as compensation for Mr. Tanen's services as a director prior to his appointment as our President. The option vested in three equal installments on each of November 1, 2009, November 1, 2010, and November 1, 2011.

(2) Option granted November 5, 2010 and vests in three equal annual installments commencing on the first anniversary of the grant date.

(3) Mr. Houchins resigned as Arno's Chief Operating Officer effective as of January 13, 2012. Unless otherwise noted, each of Mr. Houchins' stock options terminated 90 days thereafter.

(4) Option granted September 17, 2007 relating to an aggregate of 99,689 shares, of which 25% vested on the first anniversary of the grant date and the remainder vested in 36 equal monthly installments thereafter.

(5) Option granted September 29, 2009 and was scheduled to vest in three equal annual installments commencing on the first anniversary of the grant date. Following the vesting of the first two installments, the final installment, relating to 66,667 shares, was forfeited as a result of Mr. Houchins' resignation.

(6) Option granted June 20, 2011 relating to an aggregate of 288,750 shares, of which 52,500 shares vested immediately, with 59,062 shares scheduled to vest on the first anniversary of the grant date and the remainder vesting in 24 equal monthly installments thereafter; however, such additional vesting, relating to an aggregate of 236,250 shares, was forfeit as a result of Mr. Houchins' resignation. To the extent vested, this stock option remained exercisable until its termination on April 13, 2012, the three-month anniversary of Mr. Houchins' resignation.

- (7) Option granted June 20, 2011 and was scheduled to vest up to one-third annually at the discretion of the Board of Directors. This stock option was forfeited in its entirety upon Mr. Houchins' resignation.
- (8) Option granted April 25, 2011 relating to an aggregate of 941,752 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) Option granted April 25, 2011 relating to an aggregate of 1,412,627 shares, of which 25% vested on the first anniversary of the grant date and the remainder vest in 24 equal monthly installments thereafter.
- (10) Option granted June 22, 2011 relating to an aggregate of 875,000 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.
- (11) Option granted June 22, 2011 relating to an aggregate of 875,000 shares, of which 25% vested on the first anniversary of the grant date and the remainder vest in 24 equal monthly installments thereafter.

### Director Compensation

Pursuant to the non-employee director compensation plan adopted by our Board of Directors, our non-employee directors are 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 30,000 shares of the Company's common stock upon their initial appointment or election to the Board; and (3) an annual stock option grant of 10,000 shares of the Company's common stock. In addition, any non-employee director designated as chairman of the Board is entitled to an annual retainer of \$10,000, the chair of the Board's audit committee is entitled to an additional annual retainer of \$8,000, and the chairs of the Board's compensation and nominating & corporate governance committees are entitled to annual retainers of \$4,000. In addition, Dr. Belldegrun receives 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 following table sets forth the compensation paid to our directors for their service in 2011.

Name	Fees earned or paid in cash	Option Awards (1)	Total
Arie S. Belldegrun, M.D.	\$ 123,958	\$ -	\$123,958
William F. Hamilton, Ph.D.	\$ 33,000	\$ -	\$33,300
Tomer Kariv	\$ 25,000	\$ -	\$25,000
Glenn Mattes	\$ -	\$ -	\$-
Yacov Reizman	\$ 25,000	\$ -	\$25,000
Steven B. Ruchefsky	\$ 25,000	\$ -	\$25,000
David M. Tanen	\$ 25,000	\$ -	\$25,000

- (1) No stock options were granted to our non-employee directors during 2011.

## **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 December 24, 2012 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.



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Name of Beneficial Owner	No. Shares of Common Stock Beneficially Owned (1)	Percent of Class (1)
Arie S. Belldegrun, M.D. (2)	11,363,359	24.1
Glenn Mattes (3)	1,760,475	4.6
Alexander Zukiwski (4)	2,091,724	5.4
David M. Tanen (5)	1,628,782	4.5
J. Chris Houchins (6)	-	-
William F. Hamilton, Ph.D. (7)	46,634	*
Tomer Kariv (8)	14,582,877	30.5
Yacov Reizman (9)	782,587	2.1
Steven B. Ruchefsky (10)	15,891,109	31.8
All current executive officers and directors as a group (10 persons)	48,766,700	63.3
Pontifax (8)	14,582,877	30.5
UTA Capital LLC (11) 100 Executive Drive, Ste. 330 West Orange, NJ 07052	3,041,917	8.1
Commercial Street Capital, LLC (10) 800 Westchester Ave. Rye Brook, NY 10573	15,891,109	31.8
Clal Insurance Co. Ltd. (12) 48 Menachem Begin St. Tel-Aviv 66180, Israel	3,127,781	8.5
Wexford Capital LP (13) 411 West Putnam Ave. Greenwich, CT 06830	3,891,777	10.5
Peter and Donna Kash (14)(15) 689 Fifth Ave., 12 <sup>th</sup> Floor New York, NY 10022	3,790,606	9.9
Auriga Investors – Montserrat Global Fund (15)(16) 5-Rue Jean Monnet L-2180 Luxembourg	7,500,000	9.9
Benjamin Domb (17) 1010 Executive Court, Suite 250 Westmont, IL 60559	2,000,000	5.2
Brio Capital Master Fund Ltd. (15)(18) c/o Brio Capital Management LLC 100 Merrick Road, Suite 401W Rockville Centre, NY 11570-4800	4,000,000	9.9

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Green Fields Offshore Inc. (19) Four Seasons Residences, Spring 19D Jl. Setiabudi Tengah Jakarta, 12910 Indonesia	2,000,000	5.2
Marjorie and David Kaufman (20) 917 Taylors Lane Mamaroneck, NY 10543	2,500,000	6.4
Maxim Partners LLC (21) c/o Maxim Group LLC 405 Lexington Avenue, 2nd Floor New York, NY 10174	2,430,000	6.0
Perceptive Life Sciences Master Fund, Ltd. (15)(22) c/o Perceptive Advisors LLC 499 Park Ave, 25 <sup>th</sup> Floor New York, NY 10022	30,000,000	9.9
Quantum Partners LP (15)(23) c/o Soros Fund Management LLC 888 Seventh Avenue New York, NY 10106	32,499,999	9.9
RJB Partners LLC (24) 40 E. Main St., Suite 822 Newark, DE 19711	2,000,000	5.2
Sabby Management, LLC (15)(25) 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	20,000,000	9.9

\* represents less than 1%.

Based upon 36,364,942 issued and outstanding shares of our common stock as of December 24, 2012.

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

- (1) 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.  
Beneficial ownership includes: (i) 516,043 shares issuable upon the exercise of stock options held by Dr. Belldegrun; (ii) 127,619 shares of our common stock, 1,166,666 shares issuable upon the conversion of Debentures, 2,333,334 shares issuable upon the exercise of Warrants, and 62,500 shares issuable upon the exercise of other warrants held by Arie and Rebecka Belldegrun as Trustees of the Belldegrun Family Trust dated February 18, 1994; (iii) 666,666 shares issuable upon the conversion of Debentures and 1,333,334 shares issuable upon the exercise of Warrants held by the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan; (iv) 317,155 shares of our common stock and 125,000 shares issuable upon the exercise of warrants held by Leumi
- (2) Overseas Trust Corporation Limited ("Leumi") as Trustee of the BTL Trust; (v) 1,000,000 shares issuable upon the conversion of Debentures and 2,000,000 shares issuable upon the exercise of Warrants held by Leumi as Trustee of the Tampere Trust; and (vi) 127,619 shares of our common stock, 500,000 shares issuable upon the conversion of Debentures, 1,000,000 shares issuable upon the exercise of Warrants, and 62,500 shares issuable upon the exercise of other 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. Richard J. Guillaume and Christopher R.P. Lees, 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.
- (3) Beneficial ownership includes 166,666 shares issuable upon conversion of Debentures, 333,334 shares issuable upon exercise of Warrants, and 1,010,475 shares issuable upon the exercise of options.
- (4) Beneficial ownership includes 500,000 shares issuable upon conversion of Debentures, 1,000,000 shares issuable upon exercise of Warrants, and 591,724 shares issuable upon the exercise of options.
- (5) Beneficial ownership includes 149,532 shares held by Mr. Tanen's minor children and 105,554 shares issuable upon the exercise of options and warrants held by Mr. Tanen.
- (6) All stock options previously held by Mr. Houchins have been terminated as a result of his resignation as Arno's Chief Operating Officer, which resignation was effective as of January 13, 2012.
- (7) Includes 36,666 shares issuable upon the exercise of stock options.  
Beneficial ownership includes: (i) 20,000 shares issuable upon the exercise of stock options held by Mr. Kariv; and (ii) 14,562,877 shares held by affiliates of Pontifax, of which Mr. Kariv is chief executive officer, including
- (8) 3,333,334 shares issuable upon the conversion of Debentures, 6,666,668 shares issuable upon the exercise of Warrants, and 1,500,000 shares issuable upon the exercise of other warrants.  
Beneficial ownership includes: (i) 20,000 shares issuable upon the exercise of stock options held by Mr.
- (9) Reizman; and (ii) 762,587 shares held by FCC Ltd., of which Mr. Reizman is chairman and chief executive officer, including 456,300 shares issuable upon the exercise of warrants.  
Beneficial ownership includes: (i) 45,000 shares issuable upon the exercise of options and warrants held by Mr.
- (10) Ruchefsky; and (ii) 15,846,109 shares held by Commercial Street Capital, LLC, of which Mr. Ruchefsky is president, including 4,166,666 shares issuable upon the conversion of Debentures, 8,333,334 shares issuable upon the exercise of Warrants, and 1,100,000 shares issuable upon the exercise of other warrants.
- (11) Includes 1,000,000 shares issuable upon the exercise of warrants.
- (12) Includes 550,000 shares issuable upon the exercise of warrants.
- (13) Beneficial ownership includes: (i) 527,613 shares of our common stock held by Kappa Investors, LLC ("Kappa"), including 108,737 shares issuable upon the exercise of warrants; and (ii) 3,364,164 shares of our common stock held by Wexford Spectrum Investors LLC, a Delaware limited liability company ("Wexford Spectrum"), including 535,995 shares issuable upon the exercise of warrants. Wexford Capital LP, a Delaware partnership

("Wexford Capital"), is a registered Investment Advisor and also serves as an investment advisor or sub-advisor to the members of Kappa and Wexford Spectrum. Wexford GP LLC ("Wexford GP") is the general partner of Wexford Capital. Mr. Charles E. Davidson and Mr. Joseph M. Jacobs are each managing and controlling members of Wexford GP.

Beneficial ownership includes: (i) 600,000 shares issuable upon the conversion of Debentures, 1,200,000 shares issuable upon the exercise of Warrants, and 50,000 shares issuable upon the exercise of other warrants held by (14) Dr. and Mrs. Kash; (ii) 1,479,635 shares, including 152,006 shares issuable upon the exercise of options and warrants, held by Dr. Kash; and (iii) 358,876 shares held by Mrs. Kash as custodian for the benefit of their minor children under the UGMA.

Notwithstanding the number of shares of our common stock shown as beneficially owned by the security holder in the table above, the Debentures and Warrants held by the security holder provide that the security holder may (15) not convert or exercise such Debentures or 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 conversion or exercise.

Represents 2,500,000 shares issuable upon the conversion of Debentures and 5,000,000 shares issuable upon the (16) exercise of Warrants. Dr. Raj Mehra holds voting and/or dispositive power over the shares held by Auriga Investors – Montserrat Global Fund.

(17) Represents 666,666 shares issuable upon the conversion of Debentures and 1,333,334 shares issuable upon the exercise of Warrants.

Represents 1,333,333 shares issuable upon the conversion of Debentures and 2,666,667 shares issuable upon the  
(18) exercise of Warrants. Shaye Hirsch holds voting and/or dispositive power over the shares held by Brio Capital Master Fund Ltd.

Represents 666,666 shares issuable upon the conversion of Debentures and 1,333,334 shares issuable upon the  
(19) exercise of Warrants. Anton Linderum holds voting and/or dispositive power over the shares held by Green Fields Offshore Inc.

Represents 833,333 shares issuable upon the conversion of Debentures and 1,666,666 shares issuable upon the  
(20) exercise of Warrants.

Beneficial ownership includes 2,270,000 shares issuable upon the exercise of warrants. Michael Rabinowitz  
(21) holds voting and/or dispositive power over the shares held by Maxim Partners LLC.

Represents 10,000,000 shares issuable upon the conversion of Debentures and 20,000,000 shares issuable upon  
(22) the exercise of Warrants. Joseph Edelman holds voting and/or dispositive power over the shares held by Perceptive Life Sciences Master Fund, Ltd.

Represents 10,833,333 shares issuable upon the conversion of Debentures and 21,666,666 shares issuable upon  
(23) 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.

Represents 666,666 shares issuable upon the conversion of Debentures and 1,333,334 shares issuable upon the  
(24) exercise of Warrants. Joseph Sanberg holds voting and/or dispositive power over the shares held by RJB Partners LLC.

Represents: (i) 4,166,666 shares issuable upon the conversion of Debentures and 8,333,334 shares issuable upon  
the exercise of Warrants held by Sabby Healthcare Volatility Master Fund, Ltd.; and (ii) 2,500,000 shares  
issuable upon the conversion of Debentures and 5,000,000 shares issuable upon the exercise of Warrants held by  
Sabby Volatility Warrant Master Fund, Ltd. Each of Sabby Healthcare Volatility Master Fund, Ltd. and Sabby  
(25) Volatility Warrant Master Fund, Ltd. (collectively, the “Sabby Funds”) has indicated to us that Hal Mintz has voting and investment power over the shares held by it. Each of the Sabby Funds has also indicated to us that Sabby Management, LLC serves as its investment manager, that Hal Mintz is the manager of Sabby Management, LLC and that each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over these shares except to the extent of any pecuniary interest therein.

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

Dr. Beldegrun and Mr. Tanen, each a current director and substantial stockholder of Arno, and Mr. Kazam, a director until September 2010 and substantial stockholder of Arno, control Two River Consulting, LLC, or TRC. Certain employees of TRC, including Mr. Tanen, our former President, Mr. Kazam, and Mr. Scott L. Navins, our Treasurer, perform substantial services for us, including without limitation operational, managerial, financial, clinical and regulatory activities for which we have historically 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 continue to utilize the services of TRC on an as needed basis. Other than the payments to TRC, we do not pay any salary or other compensation to Messrs. Tanen, Kazam and Navins for their services to us.

Mr. Kazam, Mr. Tanen and Mr. Peter M. Kash, a director of Arno until April 2011, are also principals of Riverbank Capital Securities, Inc., a FINRA member broker dealer that acted as our placement agent in connection with our September 2010 and June 2008 private placements. Additionally, Mr. Navins, our Treasurer, is also the Financial and Operations Principal of Riverbank. In consideration for its services in connection with the September 2010 private placement, we paid Riverbank a placement fee of approximately \$789,880 and issued to designees of Riverbank five-year warrants to purchase an aggregate of 664,880 shares of Series A Preferred Stock at an initial exercise price of \$1.10 per share. Riverbank did not receive any selling commission for its services in connection with the June 2008 private placement, but received a non-accountable expense allowance of \$100,000.

Pursuant to a Consulting Agreement entered into between Arno and Fountainhead Capital Management Limited, we paid a \$500,000 consulting fee to Fountainhead Capital upon completion of the merger with Laurier. Fountainhead Capital Management was a significant stockholder of Laurier at the time of the merger.

## **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, 2011 and 2010, and for the years then ended, and for the period from August 1, 2005 (inception) through December 31, 2011, 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 that 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.

(A DEVELOPMENT STAGE COMPANY)

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ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

**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. (a development stage company) as of December 31, 2011 and 2010, and the related statements of operations and deficit accumulated during the development stage, stockholders' equity, and cash flows for the years then ended and for the period from August 1, 2005 (inception) through December 31, 2011. 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 Arno Therapeutics, Inc. (a development stage company) as of December 31, 2011 and 2010, and the results of its operations and its cash flows for the years then ended and the period from August 1, 2005 (inception) through December 31, 2011, 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 is in the development stage, has not

generated any revenues and has recurring net losses from operations. These events raise substantial doubt about the Company's 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.

/s/ Crowe Horwath LLP

New York, New York

March 30, 2012

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## ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## BALANCE SHEETS

	December 31, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 6,678,344	\$ 13,528,444
Prepaid expenses and other current assets	296,948	247,500
Total current assets	6,975,292	13,775,944
Property and equipment, net	38,673	30,013
Restricted cash	-	44,018
Security deposit	10,455	-
Total assets	\$ 7,024,420	\$ 13,849,975
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 683,161	\$ 554,362
Accrued expenses and other current liabilities	1,188,041	1,354,967
Due to related party	84,756	69,298
Deferred rent	7,351	14,748
Total current liabilities	1,963,309	1,993,375
Warrant liability	3,705,472	3,420,780
Total liabilities	5,668,781	5,414,155
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$0.0001 par value, 35,000,000 shares authorized, 0 and 15,274,000 shares issued and outstanding	-	1,527
Common stock, \$0.0001 par value, 80,000,000 shares authorized, 36,304,942 and 20,412,024 shares issued and outstanding	3,605	2,041
Additional paid-in capital	36,865,034	36,036,139
Deficit accumulated during the development stage	(35,513,000)	(27,603,887)
Total stockholders' equity	1,355,639	8,435,820
Total liabilities and stockholders' equity	\$ 7,024,420	\$ 13,849,975

See accompanying notes to financial statements

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## ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## STATEMENTS OF OPERATIONS

	Year ended December 31,		Period from
	2011	2010	August 1, 2005 (inception) through December 31, 2011
Operating expenses:			
Research and development	\$5,690,836	\$4,139,554	\$ 28,308,078
General and administrative	1,956,115	886,591	7,043,941
Total operating expenses	7,646,951	5,026,145	35,352,019
Loss from operations	(7,646,951 )	(5,026,145 )	(35,352,019 )
Other income (expense):			
Interest income	28,771	19,339	406,271
Interest expense	-	-	(1,260,099 )
Other (expense) income	(290,933 )	983,780	692,847
Total other income (expense)	(262,162 )	1,003,119	(160,981 )
Net loss	\$(7,909,113 )	\$(4,023,026 )	\$ (35,513,000 )
Preferred stock dividends	\$81,651	\$237,423	
Net loss available to common stockholders	\$(7,990,764 )	\$(4,260,449 )	
Net loss per share - basic and diluted	\$(0.23 )	\$(0.21 )	
Weighted-average shares outstanding -basic and diluted	34,514,594	20,412,024	

See accompanying notes to financial statements

## ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIENCY)

Period from August 1, 2005 (inception) through December 31, 2011

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL		
Issuance of common shares to founders at \$0.0001 per share	-	\$-	9,968,797	\$ 997	\$ 4,003	\$-	\$ 5,000
Stock based compensation for services	-	-	-	-	9,700	-	9,700
Net loss, period from August 1, 2005 (inception) through December 31, 2006	-	-	-	-	-	(370,893 )	(370,893 )
Balance at December 31, 2006	-	-	9,968,797	997	13,703	(370,893 )	(356,193 )
Stock based compensation for services	-	-	-	-	88,300	-	88,300
Net loss, year ended December 31, 2007	-	-	-	-	-	(3,359,697 )	(3,359,697 )
Balance at December 31, 2007	-	-	9,968,797	997	102,003	(3,730,590 )	(3,627,590 )

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Common stock sold in private placement, net of issuance costs of \$141,646	-	-	7,360,689	736	17,689,301	-	17,690,037
Conversion of notes payable upon closing of private placement	-	-	1,962,338	196	4,278,322	-	4,278,518
Note discount arising from note conversion	-	-	-	-	475,391	-	475,391
Warrants issued in connection with note conversion	-	-	-	-	348,000	-	348,000
Reverse merger transaction - elimination of accumulated deficit	-	-	-	-	(120,648 )	-	(120,648 )
previously issued Laurier common stock	-	-	1,100,200	110	120,538	-	120,648
Warrants issued for services	-	-	-	-	480,400	-	480,400
Stock based compensation for services	-	-	-	-	1,131,218	-	1,131,218
Net loss, year ended December 31, 2008						(12,913,566 )	(12,913,566 )
Balance at December 31, 2008	-	-	20,392,024	2,039	24,504,525	(16,644,156 )	7,862,408
Stock based compensation for services	-	-	-	-	647,448	-	647,448
	-	-	20,000	2	2,598	-	2,600

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Stock option exercise							
Net loss, year ended December 31, 2009						(6,936,705 )	(6,936,705 )
Balance at December 31, 2009	-	-	20,412,024	2,041	25,154,571	(23,580,861 )	1,575,751
Stock based compensation for services	-	-	-	-	249,286	-	249,286
Convertible preferred units issued in private placement, net of issuance costs of \$1,299,770	15,274,000	1,527	-	-	13,507,983	-	13,509,510
Warrants issued in connection with convertible preferred units issued in private placement	-	-	-	-	(3,340,421 )	-	(3,340,421 )
Warrants issues to placement agents in connection with private placement	-	-	-	-	464,720	-	464,720
Net loss, year ended December 31, 2010	-	-	-	-	-	(4,023,026 )	(4,023,026 )
Balance at December 31, 2010	15,274,000	1,527	20,412,024	2,041	36,036,139	(27,603,887 )	8,435,820
Stock based compensation for services	-	-	-	-	707,284	-	707,284
Preferred stock conversion	(15,274,000)	(1,527 )	15,274,000	1,527	-	-	-



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Issuance of stock dividend in connection with conversion of preferred stock	-	-	319,074	32	(32	)	-	-
Grant of restricted shares	-	-	250,000	-	115,168	-	-	115,168
Stock option exercise	-	-	49,844	5	6,475	-	-	6,480
Net loss, year ended December 31, 2011	-	-	-	-	-	-	(7,909,113	) (7,909,113
Balance at December 31, 2011	-	\$-	36,304,942	\$ 3,605	\$ 36,865,034	\$ (35,513,000	) \$ 1,355,639	

See accompanying notes to financial statements

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## ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## STATEMENTS OF CASH FLOWS

	Year ended December 31,		Period from
	2011	2010	August 1, 2005
			(inception)
			through December 31,
			2011
Cash flows from operating activities			
Net loss	\$(7,909,113 )	\$(4,023,026 )	\$ (35,513,000 )
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	11,677	11,554	101,144
Stock-based compensation	822,452	249,286	2,948,404
Warrant liability	284,692	80,359	365,051
Write-off of intangible assets	-	-	85,125
Warrants issued for services	-	-	480,400
Warrants issued in connection with note conversion	-	-	348,000
Note discount arising from beneficial conversion feature	-	-	475,391
Deferred rent	(7,397 )	(1,322 )	7,351
Loss on disposal of assets	2,677	-	5,357
Noncash interest expense	-	-	311,518
Changes in operating assets and liabilities			
Prepaid expenses and other assets	(49,448 )	(136,911 )	(296,948 )
Restricted cash	44,018	-	-
Security deposit	(10,455 )	-	(10,455 )
Accounts payable	128,799	(448,668 )	683,161
Accrued expenses	(166,926 )	798,763	1,188,041
Due to related party	15,458	(63,120 )	84,756
Net cash used in operating activities	(6,833,566 )	(3,533,085 )	(28,736,704 )
Cash flows from investing activities			
Purchase of property and equipment	(23,014 )	-	(100,174 )
Cash paid for intangible assets	-	-	(85,125 )
Proceeds from related party advance	-	-	525,000
Repayment of related party advance	-	-	(525,000 )
Net cash used in investing activities	(23,014 )	-	(185,299 )
Cash flows from financing activities			
Proceeds from issuance of common stock to founders	-	-	5,000

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Proceeds from issuance of preferred stock in private placement, net	-	13,974,230	13,974,230
Proceeds from issuance of common stock in private placement, net	-	-	17,690,037
Deferred financing fees paid	-	-	(45,000 )
Proceeds from issuance of notes payable	-	-	1,000,000
Repayment of notes payable	-	-	(1,000,000 )
Proceeds from issuance of convertible notes payable	-	-	3,967,000
Proceeds from exercise of stock options	6,480	-	9,080
Net cash provided by financing activities	6,480	13,974,230	35,600,347
Net (decrease) increase in cash and cash equivalents	(6,850,100 )	10,441,145	6,678,344
Cash and cash equivalents at beginning of period	13,528,444	3,087,299	-
Cash and cash equivalents at end of period	\$6,678,344	\$13,528,444	\$ 6,678,344
Supplemental schedule of cash flows information:			
Cash paid for interest	\$-	\$-	\$ 80,000
Supplemental schedule of non-cash investing and financing activities:			
Conversion of notes payable and interest to common stock	\$-	\$-	\$ 4,278,518
Common shares of Laurier issued in reverse merger transaction	\$-	\$-	\$ 110
Issuance of warrants in connection with private placement of convertible preferred units	\$-	\$3,340,421	\$ 3,340,421
Preferred stock dividends paid in connection with conversion	\$319,074	\$-	\$ 319,074

See accompanying notes to financial statements

ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO FINANCIAL STATEMENTS

Years ended December 31, 2011 and 2010 and the period

from August 1, 2005 (inception) to December 31, 2011

## **1. DESCRIPTION OF BUSINESS**

Arno Therapeutics, Inc. (“Arno” or the “Company”) develops innovative drug candidates for the treatment of patients with cancer. The following is a summary of the Company’s product development pipeline:

***Onapristone*** – Onapristone is an anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in breast cancer. In prior 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, the Company intends to develop a companion diagnostic product to identify patients who express activated progesterone and would therefore be more likely to benefit from treatment with onapristone. The Company plans to conduct pre-clinical toxicology studies and manufacturing activities and to file an investigational new drug application (“IND”) in 2013.

***AR-42*** – AR-42 is 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 is currently being studied in an investigator-initiated Phase I/II clinical study in adult subjects with relapsed or refractory hematological malignancies.

***AR-12*** – AR-12 is a potentially first-in-class, orally available, targeted anti-cancer agent that has been shown in pre-clinical studies to inhibit phosphoinositide dependent protein kinase-1, or PDK-1, a protein in the PI3K/Akt pathway that is involved in the growth and proliferation of cells, including cancer cells. AR-12 has also been reported to cause cell death through the induction of endoplasmic reticulum stress and work is ongoing to further understand the mechanism of action. The Company is currently conducting a multi-centered Phase I clinical study of AR-12 in adult subjects with advanced or recurrent solid tumors or lymphoma.

***AR-67*** – AR-67 is a novel, third-generation camptothecin analogue that inhibits Topoisomerase I activity with enhanced stability in the lactone form. AR-67 is currently being studied in a Phase II clinical study in subjects with glioblastoma multiforme, or GBM, a highly aggressive form of brain cancer. Due to the low response rate among patients in the study, the Company has determined not to proceed with further development of AR-67 beyond the ongoing Phase II study and instead plans to focus its available resources on its other programs, particularly

onapristone and AR-42.

The Company was incorporated in Delaware in March 2000 under the name 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.

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## **2. LIQUIDITY AND CAPITAL RESOURCES**

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2011, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying financial statements have been prepared in accordance with the provisions of Accounting Standards Codification (“ASC”) 915, “*Development Stage Entities*.” The Company has experienced net losses since its inception and has an accumulated deficit of approximately \$35.5 million at December 31, 2011. The Company expects to incur substantial and increasing losses and have negative net cash flows from operating activities as it expands its technology portfolio and engages in further research and development activities, particularly the conducting of pre-clinical and clinical trials.

Cash resources as of December 31, 2011 were approximately \$6.7 million, compared to \$13.5 million as of December 31, 2010. Based on its resources at December 31, 2011 and the current plan of expenditure on continuing development of the Company’s current product candidates, the Company believes that it has sufficient capital to fund its operations through approximately the third quarter of 2012. However, the Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company’s continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license 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 success of the Company depends on its ability to discover and develop new products to the point of FDA approval and subsequent revenue generation and, accordingly, to raise enough capital to finance these developmental efforts. Management plans to raise additional equity capital or license one or more of its products to finance the continued operating and capital requirements of the Company. Amounts raised will be used to further develop the Company’s products, acquire additional product licenses and for other working capital purposes. While the Company will extend its best efforts to raise additional capital to fund all operations for the next 12 to 24 months, management can provide no assurances that the Company will be able to raise sufficient funds.

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 (defined below) 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. See “Note 8. Convertible Notes Payable.”

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.

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.

**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, 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) Restricted Cash**

In October 2008, the Company entered into a non-cancelable five year office lease agreement. In connection with the lease, the Company delivered an irrevocable stand-by and unconditional letter of credit in the amount of approximately \$44,000 (or the approximate equivalent of three months' rent) with the landlord as the beneficiary as a security deposit in case of default or failure to comply with the lease requirements. In order to fund the letter of credit, the Company deposited a compensating balance of approximately \$44,000 into an interest bearing certificate of deposit with a financial institution. The Company terminated this lease agreement effective as of December 31, 2011.

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**(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

**(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 warrant liability. The carrying amounts of these instruments reasonably approximate their fair values due to their short-term maturities.

**(g) Warrant Liability**

The Company accounts for the warrants issued in connection with the September 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.

**(k) Loss per Common Share**

Basic loss per share is computed by dividing the loss available to common shareholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similarly to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

	For the Year Ended December 31,			2010		
	Loss	Shares	Per Share	Loss	Shares	Per Share
	(Numerator)	(Denominator)	Amount	(Numerator)	(Denominator)	Amount
Net loss	\$ (7,909,113)			\$ (4,023,026)		
Less: Preferred stock dividends	(81,651 )			(237,423 )		
<b>Basic and Diluted EPS</b>						
Loss available to common stockholders	\$ (7,990,764)	34,514,594	\$ (0.23 )	\$ (4,260,449)	20,412,024	\$ (0.21 )

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

Potentially dilutive securities include:

	December 31, 2011	December 31, 2010
Options to purchase common stock	–	129,532

For the year ended December 31, 2011 and 2010, 15,817,737 and 24,333,650 shares of Convertible Preferred Stock, warrants and options have been excluded from the computation of potentially dilutive securities, respectively, as their conversion and/or exercise prices are greater than the fair market price per common share as of December 31, 2011 and 2010, respectively.

**(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.

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 2011 and 2010 respectively. In addition, the Company had no amounts accrued for interest and penalties as of December 31, 2011 and 2010, respectively.

#### **(n) Recently Issued Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board ("FASB") issued additional guidance relating to fair value measurement and disclosure requirements. For fair value measurements categorized in Level 3 of the fair value hierarchy, the new guidance requires (1) disclosure of quantitative information about unobservable inputs; (2) a description of the valuation processes used by the entity; and (3) a qualitative discussion about the sensitivity of the fair value measurements to changes in unobservable inputs and interrelationships between those unobservable inputs, if any. Entities must report the level in the fair value hierarchy of assets and liabilities that are not recorded at fair value in the statement of financial position but for which fair value is disclosed. The new requirements clarify that the concepts of highest and best use and valuation premise only apply to measuring fair value of nonfinancial assets. The new requirements also specify that in the absence of a Level 1 input, a reporting entity should incorporate a premium or discount in a fair value measurement if a market participant would take into account such an input in pricing an asset or liability. Additionally, the new guidance introduces an option to measure certain financial assets and financial liabilities with offsetting positions on a net basis if certain criteria are met. For public entities, these new requirements become effective for interim and annual periods beginning on or after December 15, 2011. These requirements are applicable to our fiscal year beginning January 1, 2012. Management does not expect this new guidance to have a material effect on the Company's financial statements.

Management does not believe that any other recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial statements.

#### **5. PROPERTY AND EQUIPMENT**

Property and equipment as of December 31, 2011 and 2010 consist of the following:

	2011	2010
Computer equipment and software	\$17,721	\$8,537
Office furniture and equipment	52,242	46,861
Leasehold improvements	8,449	7,206
Total property and equipment	78,412	62,604
Accumulated depreciation	(39,739)	(32,591)

Total property and equipment, net \$38,673 \$30,013

Depreciation expense for the years ended December 31, 2011, 2010, and the period from August 1, 2005 (inception) through December 31, 2011, were \$11,677, \$11,554 and \$56,143, respectively.

## **6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY**

### **(a) 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 onapristone with the exception of France; provided, however, that the Company has an option to acquire French commercial rights from Invivis upon notice to Invivis together with a cash payment.

The onapristone license agreement provides the Company with exclusive, worldwide rights to a U.S. 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 Company will make the first milestone payment to Invivis upon the dosing of the first subject in the first company sponsored Phase 1 clinical trial of onapristone, which is not anticipated until 2013. 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, Invivis will provide 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.

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.

**(b) 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-42 and AR-12 for all therapeutic uses.

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 Phase I clinical trial. 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 may be required to make milestone payments of up to approximately \$0.2 million under these license agreements during 2012, depending on the outcome of certain ongoing development activities.

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.

(c) **AR-67 License Agreement**

The Company's rights to AR-67 were governed by an October 2006 license agreement with the University of Pittsburgh ("Pitt"). Under this agreement, Pitt granted the Company an exclusive, worldwide, royalty-bearing license for the rights to commercialize technologies embodied by certain issued patents, patent applications and know-how relating to AR-67 for all therapeutic uses.

Under the terms of the license agreement with Pitt, the Company made a one-time cash payment of \$350,000 to Pitt and reimbursed it for past patent expenses of approximately \$373,000. Additionally, Pitt was entitled to receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to AR-67. The Company would have made the first milestone payment to Pitt upon the acceptance of the first new drug application by the FDA for AR-67. The Company was also required to pay to Pitt an annual maintenance fee of \$200,000 upon the third and fourth anniversaries, \$250,000 upon the fifth and sixth anniversaries, and \$350,000 upon the seventh anniversary and annually thereafter and to pay Pitt a royalty equal to a percentage of net sales of AR-67, pursuant to the license agreement. The Company does not anticipate making any milestone payments during 2012 under this license agreement.

Under the license agreement with Pitt, the Company also agreed to indemnify and hold Pitt and its affiliates harmless from any and all claims, actions, demands, judgments, losses, costs, expenses, damages and liabilities (including reasonable attorneys' fees) arising out of or in connection with (i) the production, manufacture, sale, use, lease, consumption or advertisement of AR-67, (ii) the practice by the Company or any affiliate or sublicensee of the licensed patent; or (iii) any obligation of the Company under the license agreement unless any such claim is determined to have arisen out of the gross negligence, recklessness or willful misconduct of Pitt.

In January 2012, Pitt provided notice to the Company that it was in default of the terms of the license agreement for failing to pay the \$250,000 annual maintenance fee. In March 2012, following the Company's determination not to proceed with further development of AR-67, the parties agreed to terminate the license agreement. See Note 16. Subsequent Events.

## **7. ACCRUED LIABILITIES**

Accrued liabilities as of December 31, 2011 and 2010 consist of the following:

	2011	2010
Accrued compensation and related benefits	\$272,342	\$103,217
Accrued research and development expense	915,699	868,000
Accrued other expense	—	383,750
Total accrued liabilities	\$1,188,041	\$1,354,967

## **8. CONVERTIBLE NOTES PAYABLE**

During February 2007, the Company completed a private placement offering of two-year 6% convertible promissory notes (the "Notes") for an aggregate principal amount of \$3,967,000. The aggregate principal amount and accrued but unpaid interest on the Notes, which totaled \$4,278,518, automatically converted upon the closing of the Company's June 2008 private placement into 1,962,338 shares of common stock at a conversion price of \$2.42, which was equal to 90% of the per share price of the shares sold in the financing. Due to the beneficial conversion feature resulting from the discounted conversion price, a discount of \$475,391 was recorded as interest expense with a corresponding credit to additional paid-in capital. In addition, in conjunction with the conversion of the convertible debt, the Company issued fully vested warrants to purchase 196,189 shares of common stock to the holders of the Notes. The warrants were valued at \$348,000 using the Black-Scholes option-pricing model and the following assumptions: exercise price \$2.42, a 3.41% risk-free interest rate, a five year contractual term, a dividend rate of 0%, and 94.30% expected volatility. The cost of the warrants was included in interest expense in the accompanying Statements of

Operations, and as an increase in additional paid-in capital.

## **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, 2011.

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, 2011:

	Fair Value December 31, 2011	Quoted Market Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Liabilities</b>				
Warrant liability	\$ 3,705,472	\$ -	\$ -	\$ 3,705,472

The fair value of the warrant liability relating to the Class A and Class B warrants issued in conjunction with the September 2010 Series A Convertible Preferred Stock financing (See Note 10(c), below) was estimated by management using a third party valuation report. The third-party estimated the value of the warrants 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. The changes in the fair value of the warrant liability are recorded in other income (expense) on the statement of operations.

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 appreciation that relate to those liabilities held at December 31, 2011:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	Warrant Liability
Balance at January 1, 2011	\$ (3,420,780 )
Purchases, sales and settlements:	
Warrants issued	-
Total gains or losses:	
Unrealized appreciation	(284,692 )
Balance at December 31, 2011	\$ (3,705,472 )

## **10. STOCKHOLDERS' EQUITY**

(a) **Common Stock**

On April 25, 2011, the Company issued 250,000 shares of restricted common stock under the Company's 2005 Stock Option Plan to its new Chief Executive Officer pursuant to his employment agreement. These shares vest in 12 equal monthly installments and have a total fair value of \$172,750, or \$0.69 per share, as estimated by management using a Monte Carlo simulation model using the significant assumptions described below in addition to a discount for the restrictions and, in doing so, utilizing a third-party valuation report. The shares are recognized as compensation expense upon vesting. The Company has recognized \$115,168 of compensation expense for the year ended December 31, 2011 in connection with the restricted shares.

On February 9, 2011, the Company issued an aggregate of 15,274,000 shares of its common stock upon the automatic conversion of all 15,274,000 of its issued and outstanding shares of Series A Convertible Preferred Stock. In accordance with their terms, the shares Series A Convertible Preferred Stock automatically converted upon the effectiveness of the Company's registration statement covering the resale under the Securities Act of 1933 of the shares of common stock issuable upon conversion of such preferred shares. See "Note 10(b) Preferred Stock," below. In addition, the Company elected to satisfy accrued dividends on the Series A Convertible Preferred Stock of \$319,074 by issuing an additional 319,074 shares of common stock.

On November 15, 2010, the Company's stockholders authorized the amendment of the Company's amended and restated certificate of incorporation in order to effect a combination (reverse split) of its common stock at a ratio not to exceed one-for-eight, provided that the Company's board of directors shall have absolute discretion to determine and fix the exact ratio of such combination (not to exceed one-for-eight) and the time at which such combination shall become effective, if ever. The Company's board of directors has taken no further action to implement a combination of our common stock and reserves the right to abandon the proposed reverse stock split in its sole discretion.

As of December 31, 2011, the Company has 36,304,942 shares of common stock issued and outstanding and an additional 15,817,737 shares of common stock reserved for issuance upon the exercise of outstanding options and warrants.

**(b) Preferred Stock**

On August 11, 2010, the Company amended and restated its certificate of incorporation, increasing the number of shares of preferred stock authorized for issuance thereunder from 10,000,000 to 35,000,000.

On September 3, 2010, the Company entered into a Securities Purchase and Registration Rights Agreement (the "Purchase Agreement"), with a number of institutional and other accredited investors pursuant to which the Company sold in a private placement an aggregate of 15,274,000 shares of newly-designated Series A Convertible Preferred Stock, par value \$0.0001 per share, or Series A Preferred Stock, at a per share purchase price of \$1.00. In accordance with the Purchase Agreement, the Company also issued two-and-one-half-year Class A warrants to purchase an aggregate of 1,221,920 shares of Series A Preferred Stock at an initial exercise price of \$1.00 per share and five-year Class B warrants to purchase an aggregate of 6,415,080 shares of Series A Preferred Stock at an initial exercise price of \$1.15 per share. The terms of the Class A and Class B 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 warrants, the exercise price of the Class A and Class B warrants will be adjusted based on the lower issuance price. The sale of the shares and warrants resulted in aggregate gross proceeds of approximately \$15.3 million, before expenses.

The terms, conditions, privileges, rights and preferences of the Series A Convertible Preferred Stock are described in a Certificate of Designation filed with the Secretary of State of Delaware on September 3, 2010.

Each share of Series A Preferred Stock was initially convertible at the holder's election into one share of common stock. Upon the effective date of the registration statement on February 9, 2011, each share of Series A Preferred Stock automatically converted into one share of common stock. In addition, all outstanding warrants to purchase Series A Preferred Stock automatically converted into warrants to purchase common stock.

Along with the holders of common stock, the holders of Series A Preferred Stock were entitled to one vote on all matters submitted to the holders of common stock for each share of common stock into which the Series A Preferred Stock would be converted as of the record date for such vote based on the conversion ratio then in effect. In addition, the holders of the Series A Preferred Stock were entitled to vote as a separate class with respect to any change in the rights of the Series A Preferred Stock, any amendment to the Company's certificate of incorporation, any increase in the number of shares of Series A Preferred Stock, or the authorization, creation or issuance of any class or series of capital stock ranking senior to or of equal seniority with the Series A Preferred Stock.

The holders of Series A Preferred Stock were entitled to an annual per share cumulative dividend equal to 5% of the original issuance price of \$1.00 per share, which dividends were payable upon the conversion of the Series A Preferred Stock into common stock, and which the Company could elect to pay in the form of additional shares of common stock in lieu of cash. The holders of Series A Preferred Stock were entitled to payment of all accrued dividends prior to the payment of any dividends to the holders of common stock. As of December 31, 2010, the amount for the preferred stock dividend was \$237,423. Following payment of such accrued dividends, the holders of Series A Preferred Stock were entitled to participate with the holders of common stock in any other dividend payment on an as-converted basis.

Upon the liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Series A Preferred Stock were entitled to be paid, prior to any payments to the holders of common stock, an amount per share equal to the sum of (i) 1.5 times the original issuance price of \$1.00 per share, plus (ii) any accrued but unpaid dividends on the Series A Preferred Stock.

Issuance costs related to the financing were approximately \$1.8 million, of which approximately \$0.5 million was non-cash for issuance of warrants ("Placement Warrants") to purchase 1,056,930 shares of the Company's common stock at 110% of the Series A Preferred Stock purchase price per share to designees of Riverbank Capital Securities, Inc. ("Riverbank"), a related party controlled by several officers and/or directors of the Company (see Note 12), and I-Bankers Securities, Inc. ("IBS"), that acted as placement agents for the Company in connection with the private placement.

On February 9, 2011, the Company's registration statement was declared effective and the 15,274,000 shares of Series A Convertible Preferred Stock converted into 15,274,000 shares of common stock. In addition, the Company elected to pay the \$319,074 in accrued dividends in shares of common stock resulting in the issuance of 319,074 shares.

**(c) Warrants**

In accordance with the Purchase Agreement, the Company issued two-and-one-half-year Class A warrants to purchase an aggregate of 1,221,920 shares of Series A Preferred Stock at an initial exercise price of \$1.00 per share and five-year Class B warrants to purchase an aggregate of 6,415,080 shares of Series A Preferred Stock at an initial exercise price of \$1.15 per share. As noted above, all outstanding warrants to purchase shares of Series A Preferred Stock automatically converted into warrants to purchase common stock on February 9, 2011, when the Company's registration statement was declared effective. 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 warrants, the exercise price will be adjusted based on the lower issuance 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 to be approximately \$3.8 million and approximately \$3.4 million at December 31, 2011 and 2010, respectively. 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 expense on the statement of operations.

Significant assumptions used at December 31, 2011 for the warrants included a weighted average term of 4 years, volatility of 120% and a risk-free interest rate of 0.83%.

Below is a table that summarizes all outstanding warrants to purchase shares of the Company's common stock as of December 31, 2011.

Grant Date	Warrants Issued	Exercise Price	Weighted Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
01/02/2008	299,063	\$ 2.42	\$ 2.42	01/02/2013	-	299,063
06/02/2008	196,189	\$ 2.42	\$ 2.42	06/02/2013	-	196,189
09/03/2010	1,221,920	\$ 1.00	\$ 1.00	03/03/2013	-	1,221,920
09/03/2010	6,415,080	\$ 1.15	\$ 1.15	09/03/2015	-	6,415,080
09/03/2010	1,056,930	\$ 1.10	\$ 1.10	<u>09/03/2015</u>	-	1,056,930
	9,189,182		\$ 1.19			9,189,182

**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 2,990,655 shares of the Company's common stock reserved for issuance under the Plan. On April 25, 2011, the Company's Board of Directors approved an amendment to the Plan to increase the number of shares of common stock issuable thereunder to 7,000,000 shares. 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 of Directors, 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, 2011, an aggregate of 51,601 shares remained available for future grants and awards under the Plan, which covers stock options, warrants and restricted awards. The Company issues unissued shares to satisfy stock options, warrants exercises and restricted stock awards.

For the years ended December 31, 2011 and 2010, 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, 2011 and 2010:

	2011		2010	
Expected Volatility	87	%	73-87	%
Expected Term	5-10 years		5-10 years	
Dividend yield	0.0	%	0.0	%
Risk-free interest rate	1.5-2.0	%	1.0-1.6	%
Stock price	\$0.69 - \$0.72		\$0.53 - \$1.00	
Forfeiture rate	0.0	%	0.0	%

The valuation assumptions were determined as follows:

Expected volatility – The expected volatility on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage.

Expected term – The expected term of the awards represents the period of time that the awards are expected to be outstanding. Management considered historical data and expectations for the future to estimate employee exercise and post vest termination behavior. Consultant options are assigned an expected term equal to the maximum term of the option grant.

Dividend yield – The estimate for annual dividends is zero, because the Company has not historically paid dividends and does not intend to in the foreseeable future.

A summary of the status of the options issued under the Plan as of December 31, 2011, and information with respect to the changes in options outstanding is as follows:

	Shares Available for Grant	Options Outstanding Stock Options	Options Outstanding Weighted-Average Exercise Price	Aggregate Intrinsic Value
Balance at January 1, 2010	1,057,414	1,913,241	\$ 1.71	
Options granted under the Plan	(440,000 )	440,000	\$ 1.00	
Options exercised	-	-	\$ -	
Options forfeited	459,938	(459,938 )	\$ 2.72	
Balance at January 1, 2011	1,077,352	1,893,303	\$ 1.36	
Shares authorized for issuance	4,009,345	-	-	
Options granted under the Plan	(5,054,317 )	5,054,317	\$ 1.03	
Restricted stock granted under the Plan	(250,000 )	-	-	
Options exercised	-	(49,844 )	\$ -	
Options forfeited	269,221	(269,221 )	\$ 1.53	
Balance at December 31, 2011	51,601	6,628,555	\$ 1.09	\$ -
Exercisable at December 31, 2011		1,991,804	\$ 1.31	\$ -

The following table summarizes information about stock options outstanding at December 31, 2011:

Outstanding Shares	Exercisable Shares
--------------------	--------------------

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Exercise Price		Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price		Weighted-Average Exercise Price
\$ 1.00	6,237,822	8.8	\$ 1.00	1,601,071	\$ 1.00
\$ 2.42	299,066	4.2	\$ 2.42	299,066	\$ 2.42
\$ 3.00	91,667	2.3	\$ 3.00	91,667	\$ 3.00
Total	6,628,555	8.6	\$ 1.09	1,991,804	\$ 1.31

Stock-based compensation costs for the years ended December 31, 2011 and 2010 and for the cumulative period from August 1, 2005 (inception) through December 31, 2011, are as follows:

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	Year Ended December 31,		Period from August 1, 2005
	2011	2010	(inception) through December 31, 2011
General and administrative	\$ 449,652	\$ 118,383	\$ 1,544,627
Research and development	372,800	130,903	1,403,777
Total	\$ 822,452	\$ 249,286	\$ 2,948,404

The fair value of options vested under the 2005 Plan was approximately \$276,985 and \$304,468 for the years ended December 31, 2011 and 2010, respectively, and approximately \$2,188,342 for the period from August 1, 2005 (inception) through December 31, 2011.

At December 31, 2011, total unrecognized estimated compensation cost related to stock options granted prior to that date was approximately \$2,375,630 which is expected to be recognized over a weighted-average vesting period of 2.5 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 underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

For the year ended December 31, 2011, the Company issued options to purchase a total of 5,054,317 shares of common stock to employees and consultants with exercise prices ranging from \$1.00 to \$2.42 and terms of up to 10 years. Of this total, 10-year options to purchase 2,354,379 shares at an exercise price of \$1.00 were issued to the Company's new President and Chief Executive Officer and 10-year options to purchase 1,750,000 shares at an exercise price of \$1.00 were issued to the Company's new Chief Medical Officer. For the year ended December 31, 2010, the Company issued options to purchase a total of 440,000 shares of common stock to members of the Company's Board of Directors, all with exercise prices of \$1.00 and 10-year terms.

## **12. RELATED PARTIES**

On June 1, 2009, the Company entered into a services agreement with Two River Consulting, LLC ("TRC") to provide various clinical development, operational, managerial, accounting and financial, and administrative services to the Company for a period of one year. David M. Tanen, the Company's then President, Secretary and director, Arie S. Belldgrun, the Chairman of the Board of Directors, and Joshua A. Kazam, a director until September 2010, are each

partners of TRC. The terms of the Services Agreement were reviewed and approved by a special committee of the Company's Board of Directors consisting of independent directors. None of the members of the special committee has any interest in TRC or the services agreement. As compensation for the services contemplated by the services agreement, the Company pays TRC a monthly cash fee of \$55,000. The services agreement with TRC expired on April 1, 2011 and until a new agreement is in place, TRC is billing the Company for actual hours worked on a monthly basis. For the second through fourth quarters of 2011, TRC billed Arno \$287,145 for services rendered, an average of approximately \$31,900 per month.

On occasion, some of the Company's expenses are paid by TRC. No interest is charged by TRC on any outstanding balance owed by the Company. For the years ended December 31, 2011 and 2010 and for the period from August 1, 2005 (inception) through December 31, 2011, total cash services and reimbursed expenses totaled \$655,923, \$765,424 and \$1,803,765, respectively. As of December 31, 2011 the Company had a payable to TRC of \$84,756, which was paid in full during the first two months of 2012.

Prior to June 1, 2009, some of the Company's expenses were paid by Two River Group Holdings, LLC ("Two River"), a company owned by three of the Company's directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. For the years ended December 31, 2011 and 2010 and for the period from August 1, 2005 (inception) through December 31, 2011 reimbursable expenses totaled \$0, \$0 and \$206,039, respectively. The Company also granted fully vested warrants to purchase 299,063 shares of its common stock at an exercise price of \$2.42 to the Two River employees who provided consultation and due diligence efforts related to the in-licensing of AR-12 and AR-42. The warrants have a five year life and are valued at \$480,400 based upon the Black-Scholes option-pricing model. As of December 31, 2011 the Company has no balance payable to Two River.

The Company utilized the services of Riverbank Capital Securities, Inc. (“Riverbank”), a FINRA member broker dealer registered with the SEC, for investment banking and other investment advisory services in connection with the June 2008 private placement and the Notes. Riverbank is an entity controlled by several partners of Two River who are also officers and/or directors of the Company. The Company paid a \$100,000 non-accountable expense allowance to Riverbank for services related to the June 2008 private placement and is not obligated to Riverbank for any future payments.

In connection with the September 2010 private placement, the Company engaged Riverbank to serve as placement agent. In consideration for its services, the Company paid Riverbank a placement fee of \$789,880. In addition, the Company issued to designees of Riverbank five-year warrants to purchase an aggregate of 664,880 shares of Series A Preferred Stock at an initial exercise price of \$1.10 per share. The warrants issued to Riverbank are in substantially the same form as the Class A and Class B Warrants issued to the investors in the private placement, except that they do not include certain anti-dilution provisions contained in the Class A and Class B Warrants.

The financial condition and results of operations of the Company, as reported, are not necessarily indicative of results that would have been reported had the Company operated completely independently.

### **13. PENSION PLAN**

On October 1, 2007, the Company adopted a 401(k) savings plan (the “401(k) Plan”) for the benefit of its employees. Under the 401(k) Plan, the Company was required to make contributions equal to 3% of eligible compensation for each eligible employee whether or not the employee contributes to the 401(k) Plan. During 2011, the Company terminated the 401(k) Plan. For the years ended December 31, 2011 and 2010 and for the cumulative period from August 1, 2005 (inception) through December 31, 2011, the Company has recorded \$0, \$0 and \$16,064 of matching contributions to the 401(k) Plan.

### **14. 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 2007 to present.

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 2011, 2010 and the period from August 1, 2005 (inception) through December 31, 2011 and as of December 31, 2011 and 2010, had no amounts accrued for interest and penalties.

At December 31, 2011, the Company had no Federal income tax expense or benefit but did have Federal tax net operating loss carry-forwards of approximately \$26.2 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, 2011 and 2010 are shown below.

	For Years Ended December 31,	
	2011	2010
Non-current deferred tax assets		
Research tax credit	\$ 1,631,000	\$ 1,484,000
Net operating loss carry forwards	11,720,000	8,996,000
Stock based compensation	848,000	767,000
Total deferred tax assets	14,199,000	11,247,000
Non-current deferred tax liability		
Depreciation and amortization	(10,000 )	(8,000 )
Total net deferred tax assets	14,189,000	11,239,000
Valuation allowance	(14,189,000 )	(11,239,000 )
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, 2011 and 2010 the Company recorded valuation allowances of \$14.2 million and \$11.2 million, respectively, representing a change in the valuation allowance of \$3.0 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, 2011 and 2010 are as follows:

	2011		2010	
	Amount	Rate	Amount	Rate
Federal tax	\$(2,689,000)	34.0 %	\$(1,368,000)	34.0 %
State tax	(390,000 )	5.9 %	(237,000 )	5.9 %
R&D Credit	(15,000 )	7.7 %	(308,000 )	7.7 %
Valuation allowance	3,446,000	(47.6)%	1,913,000	(47.6)%
Net	\$-	-	\$-	-

There was no income tax benefit recorded for the years ended December 31, 2011 and 2010.

On January 20, 2010, the Company received net proceeds of \$322,016 through the sale of its New Jersey net operating losses (“NOLS”). In June 2009, the Company submitted an application with the New Jersey Economic Development Authority (“NJEDA”) to sell its 2008 NOLS in return for cash consideration to the Company. The NJEDA in conjunction with the State of New Jersey offers financing and business incentives to New Jersey-based biotechnology and technology companies. As a result of the sale of the NOLS sale, the Company’s New Jersey deferred tax asset carryforward is reduced by \$4,000,000 beginning in 2010. The Company’s federal net operating losses were not affected by the sale of the NOLS, and thus has the full value of the 2009 deferred tax asset carryforward.

On October 29, 2010, the Company was awarded funding of a total of approximately \$733,000 under the IRS Qualifying Therapeutic Discovery Project (“QTDP”) program, which was created as part of the Patient Protection and Affordable Care Act of 2010 (the “Healthcare Reform Act”). As enacted under the Healthcare Reform Act, the QTDP program provides a tax credit or grant of up to 50% of eligible costs and expenses for the tax years of 2009 and 2010 for qualifying research and development expenses incurred for innovative projects that are determined by the U.S. Department of Health and Human Services to have reasonable potential to result in a new therapy, reduce health care costs, or represent a significant advance in finding a cure for human disease. The Company was awarded approximately \$244,000 for R&D expenses incurred for each of its AR-12, AR-42 and AR-67 development programs. The Company received the total award amount of \$733,438 during November 2010.



**15. COMMITMENTS AND CONTINGENCIES**

On March 31, 2011, the Company exercised its early termination option on the Parsippany, NJ office lease, submitting written notice to the landlord and making a payment of \$53,641. The Company continued to make monthly lease payments under the Parsippany lease through December 31, 2011, at which time, this lease terminated.

On August 4, 2011, the Company entered into a lease for new 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. 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, 2011 are approximately \$277,311, 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 \$7,351 in rent expense for the Flemington Lease for the year ended December 31, 2011.

Future minimum lease payments under operating leases as of December 31, 2011 are as follows:

2012	\$59,708
2013	69,981
2014	71,816
2015	8,734

Total  
future  
minimum  
lease  
payments \$210,239

On April 21, 2011, the Company entered into an employment agreement with Glenn Mattes, as its Chief Executive Officer, with an effective commencement date of employment beginning on April 25, 2011. The agreement provides for a term of three years, expiring on April 25, 2014, and initial base salary of \$100,000. On and after the first anniversary date of the effective commencement date, Mr. Mattes' base salary shall be increased to \$350,000. In addition, Mr. Mattes is eligible to receive an annual target performance bonus of up to 50% of his base salary, but up to \$175,000 during the first year of employment. Additionally, the Company shall issue to Mr. Mattes, 250,000 shares of restricted common stock. These shares vest in 12 equal monthly installments and have a total fair value of \$172,750, or \$0.69 per share, as estimated by management using a Monte Carlo simulation model using the significant assumptions described below in addition to a discount for the restrictions and, in doing so, utilizing a third-party valuation report. The shares are recognized as compensation expense upon vesting. The Company has recognized \$115,168 of compensation expense for the year ended December 31, 2011 in connection with the restricted shares.

In addition, Mr. Mattes was granted 10-year options to purchase a total of 2,354,379 shares of the Company's common stock at an exercise price equal to \$1.00 per share. Options relating to 60% of such shares are designated as "Employment Options" and options relating to the remaining 40% of the shares are designated as "Performance Options." The right to purchase 25% of the shares subject to the Employment Options will vest and become exercisable on April 25, 2012, and thereafter the remaining shares subject to the Employment Options will vest and become exercisable in 24 equal monthly installments. The right to purchase the shares subject to the Performance Options shall vest and become exercisable, if at all, in three equal annual installments during the Term, subject to the successful achievement of specific performance objectives to be established by the Board. The Employment Options, Performance Options, and Restricted Shares were awarded to Mr. Mattes pursuant to the Plan. The employment agreement also entitles Mr. Mattes to certain change of control and severance benefits.

On June 22, 2011, the Company entered into an employment agreement with Alexander Zukiwski, M.D., as its Chief Medical Officer, with an effective commencement date of employment beginning on June 22, 2011. The agreement provides for a term of three years, expiring on June 22, 2014, and initial base salary of \$375,000. 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. The Company has 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. As of March 20, 2012, Dr. Zukiwski has not relocated to the northern New Jersey area and the Company has not reimbursed him for any moving expenses.

In addition, Dr. Zukiwski was granted 10-year options to purchase a total of 1,750,000 shares of the Company's common stock at an exercise price equal to \$1.00 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 will vest and become exercisable on June 22, 2012, and thereafter the remaining shares subject to the Employment Options will vest and become exercisable in 24 equal monthly installments. The right to purchase the shares subject to the Performance Options shall vest and become exercisable, if at all, in three equal annual installments during the Term, subject to the successful achievement of specific performance objectives to be established by the Board. The employment agreement also entitles Dr. Zukiwski to certain change of control and severance benefits.

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, 2011 is approximately \$1.9 million, all expected to be due during 2012.

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, 2011. The Company does not anticipate recognizing any significant losses relating to these arrangements.

## **16. SUBSEQUENT EVENTS**

On January 4, 2012, J. Chris Houchins, the Chief Operating Officer of the Company resigned his employment with the Company, effective as of January 13, 2012. As a result of Mr. Houchins' resignation, 539,167 stock options were forfeited.

On February 13, 2012 (the "Effective Date"), the Company, entered into a license agreement (the "License Agreement") with Invivis Pharmaceuticals, Inc. ("Invivis"), pursuant to which the Company was granted an exclusive, worldwide (except as noted below), royalty-bearing license for the rights to commercialize technologies embodied by a certain patent application and know-how relating to onapristone, an anti-progestin hormone blocker, for all therapeutic uses. Also on February 13, 2012, the Company entered into a services agreement (the "Services Agreement") with Invivis, pursuant to which Invivis will provide the Company with certain support services relating to the development of onapristone in exchange for a monthly cash payment.

Under the terms of the License Agreement, the Company is required to make a one-time cash payment of \$500,000 to Invivis within 30 days of the Effective Date. The License Agreement also requires the Company to make performance-based cash payments to Invivis of up to an aggregate of \$15.1 million upon successful completion of clinical and regulatory milestones relating to onapristone (including regulatory approval in the United States, the EU and Japan) and to pay Invivis a royalty on net sales of onapristone at a rate in the low-single digits. Pursuant to a separate services agreement, the Company will also pay Invivis a monthly fee for two years for certain clinical development support services, which includes the assignment of up to two full-time employees to perform such services.

Pursuant to the License Agreement, Invivis retains all rights related to the commercialization of onapristone in France, subject to the Company's right to engage in the clinical development of onapristone and obtain marketing approval of the drug in France. In the event the Company successfully obtains marketing approval of onapristone in France, Invivis shall have the option, within 90 days of such approval, to transfer to the Company all rights related to the commercialization of onapristone in France in exchange for a one-time cash payment.

The License Agreement provides that the Company will indemnify and hold Invivis and its affiliates harmless from any and all claims arising out of or in connection with (i) the death of or injury to any person or any damage to property; (ii) the production, manufacture, sale, use, lease, consumption or advertisement of onapristone; or (iii) any obligation of the Company under the License Agreement, except for (x) claims that the licensed patent rights infringe third party intellectual property; and (y) claims arising out of the gross negligence or willful misconduct of Invivis, breach of warranty by Invivis, or certain other breaches of the License Agreement by Invivis. The License Agreement will terminate upon the later of (i) the expiration of the last patent relating to onapristone, and (ii) February 13, 2032. Invivis may terminate the License Agreement 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 License Agreement for any reason upon 90 days' prior written notice.

On January 12, 2012, the Company received a notice from Pitt, from which the Company licensed its rights to AR-67, indicating that the Company was in default under its license agreement for failure to pay a \$250,000 annual license fee under the terms of that agreement and providing the Company with 60 days notice to remedy the default. On March 29, 2012, following the Company's determination not to proceed with further development of AR-67, the parties agreed to terminate the license agreement. The Company is currently working with Pitt to wind down its AR-67 program, and intends to fulfill its ongoing obligations in connection with the completion of the Phase II GBM study.

## ARNO THERAPUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## CONDENSED BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 593,632	\$ 6,678,344
Prepaid expenses and other current assets	331,393	296,948
Total current assets	925,025	6,975,292
Property and equipment, net	28,261	38,673
Security deposit	10,455	10,455
Total assets	\$ 963,741	\$ 7,024,420
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 2,179,437	\$ 683,161
Accrued expenses and other current liabilities	1,077,836	1,188,041
Due to related party	24,658	84,756
Deferred rent	13,602	7,351
Total current liabilities	3,295,533	1,963,309
Warrant liability	1,599,493	3,705,472
Total liabilities	4,895,026	5,668,781
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Preferred stock, \$0.0001 par value, 35,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.0001 par value, 80,000,000 shares authorized, 36,334,942 and 36,304,942 shares issued and outstanding	3,608	3,605
Additional paid-in capital	37,436,685	36,865,034
Deficit accumulated during the development stage	(41,371,578	) (35,513,000 )
Total stockholders' (deficit) equity	(3,931,285	) 1,355,639

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Total liabilities and stockholders' (deficit) equity	\$ 963,741	\$ 7,024,420
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See accompanying notes to the unaudited condensed financial statements.

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## ARNO THERAPUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from August 1, 2005 (inception) through September 30, 2012
	2012	2011	2012	2011	
Operating expenses:					
Research and development	\$ 2,067,857	\$ 1,422,662	\$ 6,286,542	\$ 3,999,469	\$ 34,594,620
General and administrative	531,431	526,732	1,685,613	1,417,381	8,729,554
Total operating expenses	2,599,288	1,949,394	7,972,155	5,416,850	43,324,174
Loss from operations	(2,599,288 )	(1,949,394 )	(7,972,155 )	(5,416,850 )	(43,324,174 )
Other income (expense):					
Interest income	658	6,680	5,898	24,104	412,169
Interest expense	-	-	-	-	(1,260,099 )
Other income (expense)	(416,010 )	184,717	2,107,679	(417,402 )	2,800,526
Total other income (expense)	(415,352 )	191,397	2,113,577	(393,298 )	1,952,596
Net loss	\$ (3,014,640 )	\$ (1,757,997 )	\$ (5,858,578 )	\$ (5,810,148 )	\$ (41,371,578 )
Preferred stock dividends	\$ -	\$ -	\$ -	\$ 81,651	
Net loss available to common stockholders	\$ (3,014,640 )	\$ (1,757,997 )	\$ (5,858,578 )	\$ (5,891,799 )	
Net loss per share - basic and diluted	\$ (0.08 )	\$ (0.05 )	\$ (0.16 )	\$ (0.17 )	
Weighted-average shares outstanding -basic and diluted	36,334,942	36,255,098	36,315,453	33,923,120	

See accompanying notes to the unaudited condensed financial statements.



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ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONDENSED STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY

PERIOD FROM AUGUST 1, 2005 (INCEPTION) TO SEPTEMBER 30, 2012

(unaudited)

	PREFERRED STOCK	COMMON STOCK	COMMON STOCK	ADDITIONAL	DEFICIT	TOTAL	
	SHARES	AMOUNT	SHARES	PAID-IN	ACCUMULATED	STOCKHOLDERS'	
			AMOUNT	CAPITAL	DURING THE	EQUITY	
					DEVELOPMENT	(DEFICIT)	
					STAGE		
Issuance of common shares to founders at \$0.0001 per share	-	\$-	9,968,797	\$ 997	\$4,003	\$-	\$ 5,000
Stock based compensation for services	-	-	-	-	9,700	-	9,700
Net loss, period from August 1, 2005 (inception) through December 31, 2006	-	-	-	-	-	(370,893 )	(370,893 )
Balance at December 31, 2006	-	-	9,968,797	997	13,703	(370,893 )	(356,193 )
Stock based compensation for services	-	-	-	-	88,300	-	88,300
Net loss, year ended December 31, 2007	-	-	-	-	-	(3,359,697 )	(3,359,697 )
	-	-	9,968,797	997	102,003	(3,730,590 )	(3,627,590 )

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Balance at December 31, 2007							
Common stock sold in private placement, net of issuance costs of \$141,646	-	-	7,360,689	736	17,689,301	-	17,690,037
Conversion of notes payable upon closing of private placement	-	-	1,962,338	196	4,278,322	-	4,278,518
Note discount arising from note conversion	-	-	-	-	475,391	-	475,391
Warrants issued in connection with note conversion	-	-	-	-	348,000	-	348,000
Reverse merger transaction - elimination of accumulated deficit	-	-	-	-	(120,648 )	-	(120,648 )
previously issued Laurier common stock	-	-	1,100,200	110	120,538	-	120,648
Warrants issued for services	-	-	-	-	480,400	-	480,400
Stock based compensation for services	-	-	-	-	1,131,218	-	1,131,218
Net loss, year ended December 31, 2008						(12,913,566 )	(12,913,566 )
Balance at December 31, 2008	-	-	20,392,024	2,039	24,504,525	(16,644,156 )	7,862,408
Stock based compensation for	-	-	-	-	647,448	-	647,448

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services

Stock option exercise	-	-	20,000	2	2,598	-	2,600
Net loss, year ended December 31, 2009						(6,936,705 )	(6,936,705 )
Balance at December 31, 2009	-	-	20,412,024	2,041	25,154,571	(23,580,861 )	1,575,751
Stock based compensation for services	-	-	-	-	249,286	-	249,286
Convertible preferred units issued in private placement, net of issuance costs of \$1,299,770	15,274,000	1,527	-	-	13,507,983	-	13,509,510
Warrants issued in connection with convertible preferred units issued in private placement	-	-	-	-	(3,340,421 )	-	(3,340,421 )
Warrants issues to placement agents in connection with private placement	-	-	-	-	464,720	-	464,720
Net loss, year ended December 31, 2010	-	-	-	-	-	(4,023,026 )	(4,023,026 )
Balance at December 31, 2010	15,274,000	1,527	20,412,024	2,041	36,036,139	(27,603,887 )	8,435,820
Stock based compensation for services	-	-	-	-	707,284	-	707,284
	(15,274,000)	(1,527 )	15,274,000	1,527	-	-	-

Preferred stock conversion							
Issuance of stock dividend in connection with conversion of preferred stock	-	-	319,074	32	(32	)	-
Grant of restricted shares	-	-	250,000	-	115,168	-	115,168
Stock option exercise	-	-	49,844	5	6,475	-	6,480
Net loss, year ended December 31, 2011	-	-	-	-	-	(7,909,113	) (7,909,113
Balance at December 31, 2011	-	-	36,304,942	3,605	36,865,034	(35,513,000	) 1,355,639
Stock based compensation for services	-	-	-	-	543,154	-	543,154
Issuance of common shares pursuant to placement agent agreement	-	-	30,000	3	28,497	-	28,500
Net loss, nine months ended September 30, 2012	-	-	-	-	-	(5,858,578	) (5,858,578
Balance at September 30, 2012	-	\$-	36,334,942	\$ 3,608	\$ 37,436,685	\$(41,371,578	) \$(3,931,285

See accompanying notes to the unaudited condensed financial statements.

## ARNO THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

## CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,		Period from August 1, 2005 (inception) through September 30, 2012
	2012	2011	
Cash flows from operating activities			
Net loss	\$ (5,858,578 )	\$ (5,810,148 )	\$ (41,371,578 )
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	10,412	8,335	111,556
Stock-based compensation	543,154	433,830	3,491,558
Warrant liability	(2,105,979 )	411,161	(1,740,928 )
Write-off of intangible assets	-	-	85,125
Warrants issued for services	-	-	480,400
Warrants issued in connection with note conversion	-	-	348,000
Note discount arising from beneficial conversion feature	-	-	475,391
Deferred rent	6,251	(10,167 )	13,602
Loss on disposal of assets	-	-	5,357
Noncash interest expense	-	-	311,518
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(5,945 )	145,705	(302,893 )
Security deposit	-	(10,455 )	(10,455 )
Accounts payable	1,496,276	101,874	2,179,437
Accrued expenses	(110,205 )	(336,462 )	1,077,836
Due to related party	(60,098 )	71,880	24,658
Net cash used in operating activities	(6,084,712 )	(4,994,447 )	(34,821,416 )
Cash flows from investing activities			
Purchase of property and equipment	-	(9,185 )	(100,174 )
Cash paid for intangible assets	-	-	(85,125 )
Proceeds from related party advance	-	-	525,000
Repayment of related party advance	-	-	(525,000 )
Net cash used in investing activities	-	(9,185 )	(185,299 )

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Cash flows from financing activities			
Proceeds from issuance of common stock to founders	-	-	5,000
Proceeds from issuance of preferred stock in private placement, net	-	-	13,974,230
Proceeds from issuance of common stock in private placement, net	-	-	17,690,037
Deferred financing fees paid	-	-	(45,000 )
Proceeds from issuance of notes payable	-	-	1,000,000
Repayment of notes payable	-	-	(1,000,000 )
Proceeds from issuance of convertible notes payable	-	-	3,967,000
Proceeds from exercise of stock options	-	-	9,080
Net cash provided by financing activities	-	-	35,600,347
Net (decrease) increase in cash and cash equivalents	(6,084,712 )	(5,003,632 )	593,632
Cash and cash equivalents at beginning of period	6,678,344	13,528,444	-
Cash and cash equivalents at end of period	\$ 593,632	\$ 8,524,812	\$ 593,632
Supplemental schedule of cash flows information:			
Cash paid for interest	\$ -	\$ -	\$ 80,000
Supplemental schedule of non-cash investing and financing activities:			
Conversion of notes payable and interest to common stock	\$ -	\$ -	\$ 4,278,518
Common shares of Laurier issued in reverse merger transaction	\$ -	\$ -	\$ 110
Issuance of warrants in connection with private placement of convertible preferred units	\$ -		\$ 3,340,421
Issuance of common stock pursuant to placement agent agreement	\$ 28,500		\$ 28,500
Preferred stock dividends settled in common stock		\$ 319,074	\$ 319,074

See accompanying notes to the unaudited condensed financial statements.

**ARNO THERAPEUTICS, INC.**

(A DEVELOPMENT STAGE COMPANY)

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

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(unaudited)

**1. DESCRIPTION OF BUSINESS**

Arno Therapeutics, Inc. (“Arno” or the “Company”) develops innovative drug candidates for the treatment of patients with cancer. The following is a summary of the Company’s product development pipeline:

***Onapristone*** – Onapristone is an anti-progestin hormone blocker that has been shown to have considerable anti-tumor activity in patients with breast cancer. In prior 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, the Company intends to develop a companion diagnostic product to selectively identify patients who express the activated form of the progesterone receptor and would potentially be more likely to benefit from treatment with onapristone. The Company is conducting pre-clinical toxicology studies and manufacturing activities in 2012 and plans to file an investigational new drug application (“IND”) or foreign equivalent in 2013.

***AR-42*** – AR-42 is 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 is currently being studied in an investigator-initiated Phase I/II clinical study in adult subjects with relapsed or refractory multiple myeloma, chronic lymphocytic leukemia, or CLL, or lymphoma. The protocol has been amended to include a solid tumor dose escalation cohort which is currently open for patient accrual.

***AR-12*** – AR-12 is an orally available, targeted anti-cancer agent that has been shown in early pre-clinical studies to inhibit phosphoinositide dependent protein kinase-1, or PDK-1, a protein in the PI3K/Akt pathway that is involved in the growth and proliferation of cells, including cancer cells. AR-12 has also been reported to cause cell death through the induction of endoplasmic reticulum stress and work is ongoing to further understand the mechanism of action. Preliminary data demonstrates that AR-12 may inhibit multiple different kinase targets. The Company is currently conducting a multi-centered Phase I clinical study of AR-12 in adult subjects with advanced or recurrent solid tumors or lymphoma.



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. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through September 30, 2012, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying condensed financial statements have been prepared in accordance with the provisions of Accounting Standards Codification (“ASC”) 915, “Development Stage Entities.” The Company has experienced net losses since its inception and has an accumulated deficit of approximately \$41.4 million at September 30, 2012. The Company expects to incur substantial and increasing losses and to have negative net cash flows from operating activities as it expands its technology portfolio and engages in further research and development activities, particularly from conducting manufacturing activities, pre-clinical studies and clinical trials.

**ARNO THERAPEUTICS, INC.**

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The accompanying unaudited Condensed Financial Statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q adopted under the Securities Exchange Act of 1934, as amended. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of Arno's management, the accompanying Condensed Financial Statements contain all adjustments (consisting of normal recurring accruals and adjustments) necessary to present fairly the financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. The interim results for the periods ended September 30, 2012 are not necessarily indicative of results for the full 2012 fiscal year or any other future interim periods. Because the Merger was accounted for as a reverse acquisition under generally accepted accounting principles, the financial statements for periods prior to June 3, 2008, reflect only the operations of Old Arno.

These unaudited Condensed Financial Statements have been prepared by management and should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission.

The preparation of financial statements in conformity with generally accepted accounting principles 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 and consultants, and estimates of the probability and potential magnitude of contingent liabilities. Actual results could differ from those estimates.

**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 office, insurance, depreciation, 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 for which development work is still in process are charged to operations as incurred and considered a component of research and development expense.

### **Warrant Liability**

The Company accounts for the warrants issued in connection with the September 2010 Purchase Agreement (see Note 7) in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company classifies 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.

### **3. LIQUIDITY AND CAPITAL RESOURCES**

Cash resources as of September 30, 2012 were approximately \$0.6 million, compared to \$6.7 million as of December 31, 2011. As of September 30, 2012, the Company had current liabilities of approximately \$3.3 million, resulting in negative working capital of approximately \$2.4 million. Accordingly, the Company is in immediate need of substantial additional financing or it may be required to cease its operations altogether. The Company's continued operations depend entirely on its ability to raise additional funds through various potential sources, such as equity or debt financing, or to license its product candidates to another pharmaceutical company. 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.

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(unaudited)

The success of the Company depends on its ability to develop new products to the point of regulatory approval and subsequent commercialization and, accordingly, to raise enough capital to finance these developmental efforts until it can achieve profitability, if ever. In order to finance the continued operating and capital requirements of the Company, management has been actively seeking to raise additional capital through the sale and issuance of its equity or debt securities or by granting a license to one or more of its products in exchange for cash payments. While the Company engaged a financial advisor in May 2012 to assist with its ongoing financing efforts, the Company does not have any committed sources of financing at this time. Amounts raised, if any, will be used to further develop the Company's product candidates, acquire rights to additional product candidates and for other working capital purposes. However, while the Company continues to extend its best efforts to raise additional capital in order to continue funding its operations, management can provide no assurances that the Company will be able to raise 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 may experience significant dilution. 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.

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.

**4. BASIC AND DILUTED LOSS PER SHARE**



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For the periods ended September 30, 2012 and 2011, 14,968,048 and 15,867,581 warrants and options have been excluded from the computation of potentially dilutive securities, respectively, as their exercise prices are greater than the fair market price per common share as of September 30, 2012 and 2011, respectively.

**5. 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 onapristone with the exception of France; provided, however, 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 Company will make the first milestone payment to Invivis upon the dosing of the first subject in the first Company-sponsored Phase I clinical trial of onapristone, which is anticipated in 2013. 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, Invivis will provide 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.

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.

#### ***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.

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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 anticipated until early 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 does not expect to be required to make any milestone payments under these license agreements during 2012.

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.

***AR-67 License Agreement***



The Company's rights to AR-67 were governed by an October 2006 license agreement with the University of Pittsburgh ("Pitt"). Under this agreement, Pitt granted the Company an exclusive, worldwide, royalty-bearing license for the rights to commercialize technologies embodied by certain issued patents, patent applications and know-how relating to AR-67 for all therapeutic uses.

In 2006, under the terms of the license agreement with Pitt, the Company made a one-time cash payment of \$350,000 to Pitt and reimbursed it for past patent expenses. Additionally, Pitt was entitled to receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to AR-67. The Company would have made the first milestone payment to Pitt upon the acceptance of the first new drug application by the FDA for AR-67. The Company was also required to pay to Pitt an annual maintenance fee of \$200,000 upon the third and fourth anniversaries of the license agreement, \$250,000 upon the fifth and sixth anniversaries, and \$350,000 upon the seventh anniversary and annually thereafter and to pay Pitt a royalty equal to a percentage of net sales of AR-67, pursuant to the license agreement.

Under the license agreement with Pitt, the Company also agreed to indemnify and hold Pitt and its affiliates harmless from any and all claims, actions, demands, judgments, losses, costs, expenses, damages and liabilities (including reasonable attorneys' fees) arising out of or in connection with (i) the production, manufacture, sale, use, lease, consumption or advertisement of AR-67, (ii) the practice by the Company or any affiliate or sublicensee of the licensed patent; or (iii) any obligation of the Company under the license agreement unless any such claim is determined to have arisen out of the gross negligence, recklessness or willful misconduct of Pitt.

On January 12, 2012, the Company received a notice from Pitt, in which Pitt claimed that the Company was in default under the parties' license agreement for failure to pay a \$250,000 annual license fee under the terms of that agreement and provided the Company with 60 days' notice to remedy the default. On March 29, 2012, following the Company's determination not to proceed with further development of AR-67, the parties agreed to terminate the license agreement. As of September 30, 2012, the Company has accrued for the outstanding annual license fee of \$250,000, while it is working to wind down its AR-67 program.

## **6. 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 September 30, 2012.

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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 September 30, 2012:

	Fair Value September 30, 2012	Quoted Market Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Warrant liability	\$ 1,599,493	\$ -	\$ -	\$ 1,599,493

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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 appreciation that relate to those liabilities held at September 30, 2012:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	Warrant Liability	
Balance at January 1, 2012	\$ (3,705,472	)
Purchases, sales and settlements Warrants issued	-	
Total gains or losses Unrealized depreciation	2,105,979	
Balance at September 30, 2012	\$ (1,599,493	)

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**ARNO THERAPEUTICS, INC.**

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**7. STOCKHOLDERS' EQUITY**

**Common Stock**

On November 15, 2010, the Company's stockholders authorized the amendment of the Company's amended and restated certificate of incorporation in order to effect a combination (reverse split) of its common stock at a ratio not to exceed one-for-eight, provided that the Company's board of directors shall have absolute discretion to determine and fix the exact ratio of such combination and the time at which such combination shall become effective, if ever. The Company's board of directors has taken no further action to implement a combination of its common stock and reserves the right to abandon the proposed reverse stock split in its sole discretion.

On February 9, 2011, all 15,274,000 shares of the Company's outstanding Series A Convertible Preferred Stock automatically converted into 15,274,000 shares of common stock upon the effectiveness of a registration statement that the Company filed with the SEC covering the resale of such conversion shares. In addition, the Company elected to pay the \$319,074 in accrued dividends on such preferred stock through the issuance of shares of common stock resulting in the issuance of an additional 319,074 shares.

On April 25, 2011, the Company issued 250,000 shares of restricted common stock to its new Chief Executive Officer pursuant to his employment agreement. These shares vested in 12 equal monthly installments and had a total fair value of \$172,750, or \$0.69 per share, as estimated by management using a Monte Carlo simulation model using the significant assumptions described below in addition to a discount for the restrictions and, in doing so, utilized a third-party valuation report (see Note 7 – Warrants). The shares were recognized as compensation expense upon vesting. The Company recognized no expense for the three months ended September 30, 2012. The Company recognized \$57,584 and \$172,752 of compensation expense for the nine months ended September 30, 2012 and for the period from August 1, 2005 (inception) through September 30, 2012, respectively, in connection with the restricted shares. As of April 25, 2012, all 250,000 shares had vested.

On June 27, 2012, the Company issued 30,000 shares of its common stock to a financial advisor as an upfront fee for providing services in connection with the Company's ongoing financing efforts. These shares were valued at \$28,500 based on the Company's per share price of \$0.95 as of May 30, 2012, the date of the advisor's engagement.

As of September 30, 2012, the Company has 36,334,942 shares of common stock issued and outstanding.

### **Preferred Stock**

On August 11, 2010, the Company amended and restated its certificate of incorporation, increasing the number of shares of preferred stock authorized for issuance thereunder from 10,000,000 to 35,000,000.

On September 3, 2010, the Company entered into a Securities Purchase and Registration Rights Agreement, or the Purchase Agreement, with a number of institutional and accredited investors pursuant to which the Company sold in a private placement an aggregate of 15,274,000 shares of newly-designated Series A Convertible Preferred Stock, par value \$0.0001 per share, or Series A Preferred Stock, at a per share purchase price of \$1.00. In accordance with the Purchase Agreement, the Company also issued two-and-one-half-year Class A warrants to purchase an aggregate of 1,221,920 shares of Series A Preferred Stock at an initial exercise price of \$1.00 per share and five-year Class B warrants to purchase an aggregate of 6,415,080 shares of Series A Preferred Stock at an initial exercise price of \$1.15 per share. The terms of the Class A and Class B 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 warrants, the exercise price of the Class A and Class B warrants will be adjusted based on the lower issuance price. The sale of the shares and warrants resulted in aggregate gross proceeds of approximately \$15.2 million, before expenses.

The terms, conditions, privileges, rights and preferences of the Series A Preferred Stock are described in a Certificate of Designation filed with the Secretary of State of Delaware on September 3, 2010.

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The Certificate of Designation provided that each share of Series A Preferred Stock was initially convertible at the holder's election into one share of common stock. The Certificate of Designation further provided that all shares of Series A Preferred Stock would automatically convert into common stock upon the effective date of a registration statement covering the resale under the Securities Act of the conversion shares of common stock. In addition, the Class A and B warrants provided that, upon the automatic conversion of the Series A Preferred Stock, such warrants would automatically convert into the right to purchase shares of common stock. On February 9, 2011, a registration statement filed under the Securities Act covering the resale of the shares of common stock issuable upon conversion of the Series A Preferred Stock was declared effective, resulting in the automatic conversion of all 15,274,000 shares of Series A Preferred Stock into an equal number of shares of common stock.

The holders of Series A Preferred Stock were entitled to an annual per share cumulative dividend equal to 5% of the original issuance price of \$1.00 per share, which dividends were paid upon the conversion of the Series A Preferred Stock into common stock, and which the Company elected to pay in the form of additional shares of common stock in lieu of cash. The accrued dividend through February 9, 2011, the effective date of the registration statement and date of conversion of the Series A Preferred Stock into common stock, was \$319,074. The dividend was paid in 319,074 shares of common stock at a \$1.00 per share conversion price.

Issuance costs related to the financing were approximately \$1.8 million, of which approximately \$0.5 million was non-cash for issuance of warrants ("Placement Warrants") to purchase 1,056,930 shares of the Company's common stock at 110% of the Series A Preferred Stock purchase price per share to designees of Riverbank Capital Securities, Inc. ("Riverbank"), a related party controlled by several officers and/or directors of the Company (see Note 9), and I-Bankers Securities, Inc. ("IBS"), which acted as placement agents for the Company in connection with the private placement. As of September 30, 2012, none of these warrants have been exercised.

**Warrants**

In accordance with the September 2010 Purchase Agreement, the Company issued two-and-one-half-year Class A warrants to purchase an aggregate of 1,221,920 shares of Series A Preferred Stock at an initial exercise price of \$1.00 per share and five-year Class B warrants to purchase an aggregate of 6,415,080 shares of Series A Preferred Stock at an initial exercise price of \$1.15 per share. 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 warrants, the exercise price will be adjusted based on the lower issuance 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 to be approximately \$1.6 million and approximately \$3.7 million at September 30, 2012 and December 31, 2011, respectively. This significant decrease compared to the December 2011 valuation is primarily attributable to a significant decrease in the trading price of the Company's common stock during 2012. 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.

In connection with the September 2010 private placement, the Company issued warrants ("Placement Warrants") to purchase 1,056,930 shares of the Company's common stock at 110% of the Series A Preferred Stock purchase price per share to designees of Riverbank and IBS, that acted as placement agents for the Company in connection with the private placement. As of September 30, 2012, none of these warrants have been exercised.

**ARNO THERAPEUTICS, INC.**

(A DEVELOPMENT STAGE COMPANY)

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2012

(unaudited)

Below is a table that summarizes all outstanding warrants to purchase shares of the Company's common stock as of September 30, 2012.

Grant Date	Warrants Issued	Exercise Price	Weighted-Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
01/02/2008	299,063	\$ 2.42	\$ 2.42	01/02/2013	-	299,063
06/02/2008	196,189	\$ 2.42	\$ 2.42	06/02/2013	-	196,189
09/03/2010	1,221,920	\$ 1.00	\$ 1.00	03/03/2013	-	1,221,920
09/03/2010	6,415,080	\$ 1.15	\$ 1.15	09/03/2015	-	6,415,080
09/03/2010	1,056,930	\$ 1.10	\$ 1.10	09/03/2015	-	1,056,930
	9,189,182		\$ 1.19		-	9,189,182

**8. 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 2,990,655 shares of the Company's common stock reserved for issuance under the Plan. On April 25, 2011, 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 7,000,000 shares. 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 of Directors, 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 September 30, 2012, an aggregate of 901,290 shares remained available for future grants and awards under the Plan, which covers stock options, warrants and restricted awards. The Company issues unissued shares to satisfy stock options, warrants exercises and restricted stock awards.

For the three and nine months ended September 30, 2012, the Company did not issue any stock options. In previous periods, 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 three and nine months ended September 30, 2011:

	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2011	
Expected volatility	87	% 86 - 87%	
Expected term	10 years	6 - 10 years	
Dividend yield	0	% 0	%
Risk-free interest rate	1.5	% 1.5 - 2.0%	
Stock price	\$0.71	\$0.69 - \$0.72	
Forfeiture rate	0.0	% 0.0	%

**ARNO THERAPEUTICS, INC.**

(A DEVELOPMENT STAGE COMPANY)

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2012

(unaudited)

A summary of the status of the options issued under the Plan at September 30, 2012, and information with respect to the changes in options outstanding is as follows:

	Shares Available for Grant	Outstanding Stock Options	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Balance at January 1, 2012	51,601	6,628,555	\$ 1.09	
Options granted under the Plan	-	-		
Options exercised	-	-		
Options forfeited	849,689	(849,689 )	\$ 1.00	
Balance at September 30, 2012	901,290	5,778,866	\$ 1.11	\$ -
Exercisable at September 30, 2012		2,652,636	\$ 1.23	\$ -

The following table summarizes information about stock options outstanding at September 30, 2012:

Exercise Price	Outstanding			Exercisable	
	Shares	Weighted- Average Remaining Contractual Life (Years)	Weighted- Average Exercise Price	Shares	Weighted- Average Exercise Price
\$ 1.00	5,388,133	8.0	\$ 1.00	2,261,903	\$ 1.00
\$ 2.42	299,066	3.7	\$ 2.42	299,066	\$ 2.42
\$ 3.00	91,667	1.5	\$ 3.00	91,667	\$ 3.00
Total	5,778,866	7.8	\$ 1.11	2,652,636	\$ 1.23

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Stock-based compensation costs under the Plan for the three and nine months ended September 30, 2012 and 2011 and for the cumulative period from August 1, 2005 (inception) through September 30, 2012 are as follows:

	Three months ended September 30,		Nine months ended September 30,		Period from August 1, 2005 (inception) through September 30, 2012
	2012	2011	2012	2011	
Research and development	\$ 84,957	\$ 56,500	\$ 197,771	\$ 125,100	\$ 1,601,548
General and administrative	96,600	141,688	345,383	308,730	1,890,010
Total	\$ 181,557	\$ 198,188	\$ 543,154	\$ 433,830	\$ 3,491,558

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**ARNO THERAPEUTICS, INC.**

(A DEVELOPMENT STAGE COMPANY)

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

September 30, 2012

(unaudited)

The fair value of options vested under the Plan was approximately \$117,228 and \$104,186 for the three months ended September 30, 2012 and 2011, respectively, approximately \$446,897 and \$230,929 for the nine months ended September 30, 2012 and 2011, respectively and approximately \$2,801,762 for the period from August 1, 2005 (inception) through September 30, 2012.

At September 30, 2012, total unrecognized estimated compensation cost related to stock options granted prior to that date was approximately \$1,470,862, which is expected to be recognized over a weighted-average vesting period of 0.7 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.

**9. RELATED PARTIES**

On June 1, 2009, the Company entered into a services agreement with Two River Consulting, LLC ("TRC") to provide various clinical development, operational, managerial, accounting and financial, and administrative services to the Company for a period of one year. David M. Tanen, a director of the Company and at the time also its President, Arie S. Belldegrun, the Chairman of the Board of Directors, and Joshua A. Kazam, a director until September 2010, are each partners of TRC. The terms of the Services Agreement were reviewed and approved by a special committee of the Company's Board of Directors consisting of independent directors. None of the members of the special committee has any interest in TRC or the services agreement. As compensation for the services contemplated by the services

agreement, the Company paid TRC a monthly cash fee of \$55,000. The services agreement with TRC expired on April 1, 2011 and until a new agreement is in place, TRC is billing the Company for actual hours worked on a monthly basis. For the nine months ended September 30, 2012, TRC billed Arno \$199,631 for services rendered, an average of approximately \$22,181 per month.

On occasion, some of the Company's expenses are paid by TRC. No interest is charged by TRC on any outstanding balance owed by the Company. For the three and nine months ended September 30, 2012 and 2011 and for the period from August 1, 2005 (inception) through September 30, 2012 services and reimbursed expenses totaled \$76,240, \$247,369, \$158,366, \$565,575 and \$2,051,134 respectively. As of September 30, 2012, the Company had a payable to TRC of \$24,658, which was paid in full during October 2012.

In connection with the September 2010 private placement, the Company engaged Riverbank to serve as placement agent. In consideration for its services, the Company paid Riverbank a placement fee of \$789,880. In addition, the Company issued to designees of Riverbank five-year warrants to purchase an aggregate of 664,880 shares of Series A Preferred Stock at an initial exercise price of \$1.10 per share. The warrants issued to Riverbank are in substantially the same form as the Class A and Class B Warrants issued to the investors in the private placement, except that they do not include certain anti-dilution provisions contained in the Class A and Class B Warrants. Each of Messrs. Kazam, Tanen and Peter M. Kash, a director of Arno until April 2011, are principals of Riverbank.

The financial condition and results of operations of the Company, as reported, are not necessarily indicative of results that would have been reported had the Company operated completely independently.

**208,815,953 Shares**

**Common Stock**

PROSPECTUS

, 2013

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee.

	Amount to be Paid
SEC registration fee	\$ 14,241
Legal fees and expenses	50,000
Accounting fees and expenses	20,000
Printing and engraving and miscellaneous expenses	5,000
Total	\$ 89,241

**ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.**

Section 145 of the General Corporation Law of the State of Delaware provides as follows:

A corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

A corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification will be made in respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify any person, including persons who are not our directors and officers, to the fullest extent permitted by Section 145 of the Delaware General Corporation Law.

In addition, pursuant to our bylaws, we will indemnify our directors and officers against expenses (including judgments or amounts paid in settlement) incurred in any action, civil or criminal, to which any such person is a party by reason of any alleged act or failure to act in his capacity as such, except as to a matter as to which such director or officer shall have been finally adjudged to be liable for negligence or misconduct in the performance of his duty to the corporation or not to have acted in good faith in the reasonable belief that his action was in the best interest of the corporation.

Reference is made to Item 17 for our undertakings with respect to indemnification for liabilities arising under the Securities Act of 1933.



## **ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.**

### **September 2010 Private Placement of Series A Preferred Stock and Warrants**

On September 9, 2010, we entered into a Securities Purchase and Registration Rights Agreement (the “2010 Purchase Agreement”) with a number of accredited investors pursuant to which we agreed to sell in a private placement up to an aggregate of 20,000,000 shares of our newly-designated Series A Convertible Preferred Stock, par value \$0.0001 per share (the “Series A Preferred Stock”), at a per share purchase price of \$1.00. Pursuant to the terms of the 2010 Purchase Agreement, we also agreed to issue to each investor a two-and-one-half-year warrant to purchase a number of additional shares of Series A Preferred Stock equal to 8% of the number of shares purchased by such investor at an initial exercise price of \$1.00 per share (collectively, the “Class A Warrants”), and a five-year warrant to purchase a number of additional shares of Series A Preferred Stock equal to 42% of the number of shares purchased by such investor at an initial exercise price of \$1.15 per share (collectively, the “Class B Warrants”). Between September 9, 2010 and September 13, 2010, we completed a number of closings under the 2010 Purchase Agreement, issuing an aggregate of 15,274,000 shares of Series A Preferred Stock, Class A Warrants to purchase 1,221,920 shares of Series A Preferred Stock, and Class B Warrants to purchase 6,415,080 shares of Series A Preferred Stock. The sale of the shares and warrants resulted in aggregate gross proceeds of approximately \$15.2 million, before deducting expenses. In connection with the private placement, we issued five-year warrants to purchase an aggregate of 1,056,930 shares of Series A Preferred Stock at an initial exercise price of \$1.10 per share to the placement agents and their designees.

The sales of the securities identified above were made pursuant to privately negotiated transactions that did not involve a public offering of securities and, accordingly, we believe that these transactions were exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof and rules promulgated thereunder. Each of the above-referenced investors in our stock represented to us in connection with their investment that they were “accredited investors” (as defined by Rule 501 under the Securities Act) and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The investors received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. On February 9, 2011, the effective date of our registration statement on Form S-1 (SEC File No. 333-170474), each share of Series A Preferred Stock automatically converted into one share of common stock and all outstanding warrants to purchase Series A Preferred Stock automatically converted into warrants to purchase common stock.

### **November 2012 Private Placement of 8% Senior Convertible Debentures and Warrants**

On November 26, 2012, we entered into a Securities Purchase Agreement (the “2012 Purchase Agreement”) with a number of institutional and accredited investors pursuant to which we sold in a private placement an aggregate

principal amount of \$14,857,200 of our three-year 8% Senior Convertible Debentures (collectively, the “Debentures”). In accordance with the 2012 Purchase Agreement, we also issued to each investor a five-year warrant to purchase, at an initial exercise price of \$0.50 per share, a number of shares of common stock equal to the principal amount of Debentures purchased by such investor divided by \$0.30 (collectively, the “Series A Warrants”). In addition to the Series A Warrants, each investor also received an 18-month warrant to purchase, at an initial exercise price of \$0.30 per share, a number of shares of common stock equal to the principal amount of Debentures purchased by such investor divided by \$0.30 (collectively, the “Series B Warrants,” and together with the Series A Warrants, the “2012 Warrants”). Pursuant to the 2012 Purchase Agreement, we issued to the investors Series A Warrants to purchase an aggregate of 49,524,003 shares of common stock, and Series B Warrants to purchase an aggregate of 49,524,003 shares of common stock. The sale of the Debentures and 2012 Warrants, which occurred in two closings on November 26, 2012 and December 18, 2012, resulted in aggregate gross proceeds of approximately \$14.9 million, before deducting placement agent fees and other transaction-related expenses of approximately \$1.2 million. In connection with the private placement, we issued 60,000 shares of common stock and five-year warrants to purchase an additional 2,270,000 shares of common stock at an initial exercise price of \$0.33 per share to an affiliate of the placement agent.

The sales of the securities identified above were made pursuant to privately negotiated transactions that did not involve a public offering of securities and, accordingly, we believe that these transactions were exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof and rules promulgated thereunder. Each of the above-referenced investors in our stock represented to us in connection with their investment that they were “accredited investors” (as defined by Rule 501 under the Securities Act) and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The investors received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

**ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.**

**(a) Exhibits.**

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger dated March 5, 2008, by and among Laurier International, Inc., Laurier Acquisition, Inc. and Arno Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K filed March 6, 2008).
2.2	Amendment No. 1 dated May 12, 2008 to Agreement and Plan of Merger by and among Laurier International, Inc., Laurier Acquisition, Inc. and Arno Therapeutics, Inc. (incorporated by reference to Exhibit 2.2 of the Registrant's Registration Statement on Form S-1 filed July 31, 2008, SEC File No. 333-152660).
2.3	Amendment No. 2 dated May 30, 2008 to Agreement and Plan of Merger by and among Laurier International, Inc., Laurier Acquisition, Inc. and Arno Therapeutics, Inc. (incorporated by reference to Exhibit 2.3 of the Registrant's Registration Statement on Form S-1 filed July 31, 2008, SEC File No. 333-152660).
3.1	Amended & Restated Certificate of Incorporation of Arno Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
3.2	Certificate of Amendment of Amended & Restated Certificate of Incorporation of Arno Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed November 27, 2012).
3.3	Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of the Registrant's Registration Statement on Form SB-2 filed October 2, 2002, SEC File No. 333-100259).
3.4	Certificate of Designation of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed June 9, 2008).
4.2	Form of Common Stock Purchase Warrant issued to former note holders of Arno Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 of the Registrant's Form 8-K filed June 9, 2008).
4.3	Form of Class A Warrant issued to investors in September 2010 private placement (incorporated by reference to Exhibit 4.3 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
4.4	Form of Class B Warrant issued to investors in September 2010 private placement (incorporated by reference to Exhibit 4.4 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
4.5	Form of Placement Agent Warrant issued in September 2010 private placement (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
4.6	Form of 8% Senior Convertible Debenture issued to investors in November 2012 private placement (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed November 27, 2012).
4.7	Form of Series A/B Warrant issued to investors in November 2012 private placement (incorporated by reference to Exhibit 4.2 of the Registrant's Form 8-K filed November 27, 2012).

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- 4.8 Form of Placement Agent Warrant issued in November 2012 private placement.
- 5.1 Opinion of Fredrikson & Byron, P.A.
- 10.1 Letter agreement dated September 12, 2007 between Arno Therapeutics, Inc. and J. Chris Houchins (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed June 9, 2008).
- 10.2 Arno Therapeutics, Inc. 2005 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q for the quarter ended June 30, 2011).
- 10.3 Form of stock option agreement for use under Arno Therapeutics, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed June 9, 2008).
- 10.4 License Agreement dated October 25, 2006 between Arno Therapeutics, Inc. and The University of Pittsburgh (incorporated by reference to Exhibit 10.5 of the Registrant's Form 8-K filed June 9, 2008).+
- 10.5 License Agreement dated January 3, 2008 between Arno Therapeutics, Inc. and The Ohio State University Research Foundation (incorporated by reference to Exhibit 10.6 of the Registrant's Form 8-K filed June 9, 2008).+
- 10.6 License Agreement dated January 9, 2008 between Arno Therapeutics, Inc. and The Ohio State University Research Foundation (incorporated by reference to Exhibit 10.7 of the Registrant's Form 8-K filed June 9, 2008).+
- 10.7 Form of Subscription Agreement between Arno Therapeutics, Inc. and the investors in the June 2, 2008 private placement (incorporated by reference to Exhibit 10.8 of the Registrant's Form 8-K filed June 9, 2008).
- 10.8 Services Agreement dated June 1, 2009, between Arno Therapeutics, Inc. and Two River Consulting, LLC (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
- 10.9 Form of Securities Purchase and Registration Rights Agreement dated September 3, 2010 among Arno Therapeutics, Inc. and the purchasers identified therein (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).
- 10.10 First Amendment to Services Agreement dated September 9, 2010, between Arno Therapeutics, Inc. and Two River Consulting, LLC (incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 filed November 8, 2010, SEC File No. 333-170474).

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- 10.11 Letter Agreement dated February 18, 2010 between Arno Therapeutics, Inc. and Two River Consulting, LLC (incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1 filed January 18, 2011, SEC File No. 333-170474).
- 10.12 Letter agreement dated August 26, 2010 between Arno Therapeutics, Inc. and J. Chris Houchins (incorporated by reference to Exhibit 10.16 of the Registrant's Registration Statement on Form S-1 filed January 18, 2011, SEC File No. 333-170474).
- 10.13 Employment Agreement by and between Arno Therapeutics, Inc. and Glenn Mattes, dated April 25, 2011 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed April 28, 2011).
- 10.14 Restricted Stock Agreement between Arno Therapeutics, Inc. and Glenn Mattes, dated April 25, 2011 (incorporated by reference to Exhibit 10.3 of the Registrant's Form 10-Q for the quarter ended June 30, 2011).
- 10.15 Stock Option Agreement (Employment Options) between Arno Therapeutics, Inc. and Glenn Mattes, dated April 25, 2011 (incorporated by reference to Exhibit 10.4 of the Registrant's Form 10-Q for the quarter ended June 30, 2011).
- 10.16 Stock Option Agreement (Performance Options) between Arno Therapeutics, Inc. and Glenn Mattes, dated April 25, 2011 (incorporated by reference to Exhibit 10.5 of the Registrant's Form 10-Q for the quarter ended June 30, 2011).
- 10.17 Indemnification Agreement by and between Arno Therapeutics, Inc. and Glenn Mattes, dated April 25, 2011 (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed April 28, 2011).
- 10.18 Employment Agreement by and between Arno Therapeutics, Inc. and Alex Zukiwski, dated June 22, 2011 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed June 28, 2011).
- 10.19 Stock Option Agreement (Employment Options) between Arno Therapeutics, Inc. and Alex Zukiwski, dated June 22, 2011 (incorporated by reference to Exhibit 10.8 of the Registrant's Form 10-Q for the quarter ended June 30, 2011).
- 10.20 Stock Option Agreement (Performance Options) between Arno Therapeutics, Inc. and Alex Zukiwski, dated June 22, 2011 (incorporated by reference to Exhibit 10.9 of the Registrant's Form 10-Q for the quarter ended June 30, 2011).
- 10.21 Exclusive License Agreement dated February 13, 2012 between Arno Therapeutics, Inc. and Invivis Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q for the quarter ended March 31, 2012).+
- 10.22 Master Services Agreement dated February 13, 2012 between Arno Therapeutics, Inc. and Invivis Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q for the quarter ended March 31, 2012).+
- 10.23 Form of Securities Purchase Agreement dated November 26, 2012 among Arno Therapeutics, Inc. and the Purchasers identified therein (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed November 27, 2012).
- 10.24 Form of Registration Rights Agreement dated November 26, 2012 among Arno Therapeutics, Inc. and the Holders identified therein (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed November 27, 2012).
- 10.25 Amendment No. 1 dated December 13, 2012 to Securities Purchase Agreement dated November 26, 2012 among Arno Therapeutics, Inc. and the Purchasers identified therein.
- 23.1 Consent of Crowe Horwath LLP
- 23.2 Consent of Fredrikson & Byron, P.A. (included in Exhibit 5.1).
- 24.1 Power of Attorney (included on signature page hereof).
- 101 The following financial information from Arno Therapeutics, Inc.'s Registration Statement on Form S-1, formatted in eXtensible Business Reporting Language (XBRL): (A) (i) Balance Sheets as of December 31, 2011 and 2010, (ii) Statements of Operations for the years ended December 31, 2011 and 2010, and for the period from August 1, 2005 (inception) through December 31, 2011, (iii) Statement of Stockholders' Equity (Deficiency) for the period from August 1, 2005 (inception) through December 31, 2011, (iv) Statements of

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Cash Flows for the years ended December 31, 2011 and 2010, and for the period from August 1, 2005 (inception) through December 31, 2011, and (v) Notes to Financial Statements; and (B) (i) Condensed Balance Sheets as of September 30, 2012 and December 31, 2011, (ii) Condensed Statements of Operations for the three and nine months ended September 30, 2012 and September 30, 2011, and for the period from August 1, 2005 (inception) through September 30, 2012, (iii) Condensed Statement of Stockholders' (Deficit) Equity for the period from August 1, 2005 (inception) through September 30, 2012, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2012 and September 30, 2011, and for the period from August 1, 2005 (inception) through September 30, 2012, and (v) Notes to Condensed Financial Statements.

<sup>+</sup> Confidential treatment has been granted as to certain omitted portions of this exhibit pursuant to Rule 406 of the Securities Act or Rule 24b-2 of the Exchange Act.

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**(b) Financial Statement Schedules.**

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Registration Statement.

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## ITEM 17. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which

(ii) was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

That, for the purpose of determining any liability under the Securities Act, each post-effective amendment shall be

(2) deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of this offering.

That, for the purpose of determining liability under the Securities Act to any purchaser, if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is

(4) part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.



Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC this form of indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against these liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of this issue.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Flemington, State of New Jersey, on December 26, 2012.

ARNO THERAPEUTICS, INC.

By: /s/ Glenn R. Mattes  
 Glenn R. Mattes  
 President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Glenn R. Mattes, David M. Tanen and Scott L. Navins, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him in his name, place and stead, in any and all capacities, to sign any or all amendments to this registration statement and additional registration statements relating to the same offering, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Glenn R. Mattes Glenn R. Mattes	President, Chief Executive Officer, and Director (Principal Executive Officer)	December 26, 2012
/s/ Scott L. Navins Scott L. Navins	Treasurer (Principal Financial and Accounting Officer)	December 26, 2012
/s/ Arie S. Belldegrun Arie S. Belldegrun, M.D.	Chairman of the Board	December 26, 2012
/s/ William F. Hamilton William F. Hamilton, Ph.D.	Director	December 26, 2012

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/s/ Tomer Kariv Tomer Kariv	Director	December 26, 2012
/s/ Yacov Reizman Yacov Reizman	Director	December 26, 2012
/s/ Steven B. Ruchefsky Steven B. Ruchefsky	Director	December 26, 2012
/s/ David M. Tanen David M. Tanen	Secretary and Director	December 26, 2012

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**INDEX TO EXHIBITS FILED WITH THIS REGISTRATION STATEMENT**

<b>Exhibit Number</b>	<b>Description of Document</b>
4.8	Form of Placement Agent Warrant issued in November 2012 private placement.
5.1	Opinion of Fredrikson & Byron, P.A.
10.25	Amendment No. 1 dated December 13, 2012 to Securities Purchase Agreement dated November 26, 2012 among Arno Therapeutics, Inc. and the Purchasers identified therein.
23.1	Consent of Crowe Horwath LLP
101	The following financial information from Arno Therapeutics, Inc.'s Registration Statement on Form S-1, formatted in eXtensible Business Reporting Language (XBRL): (A) (i) Balance Sheets as of December 31, 2011 and 2010, (ii) Statements of Operations for the years ended December 31, 2011 and 2010, and for the period from August 1, 2005 (inception) through December 31, 2011, (iii) Statement of Stockholders' Equity (Deficiency) for the period from August 1, 2005 (inception) through December 31, 2011, (iv) Statements of Cash Flows for the years ended December 31, 2011 and 2010, and for the period from August 1, 2005 (inception) through December 31, 2011, and (v) Notes to Financial Statements; and (B) (i) Condensed Balance Sheets as of September 30, 2012 and December 31, 2011, (ii) Condensed Statements of Operations for the three and nine months ended September 30, 2012 and September 30, 2011, and for the period from August 1, 2005 (inception) through September 30, 2012, (iii) Condensed Statement of Stockholders' (Deficit) Equity for the period from August 1, 2005 (inception) through September 30, 2012, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2012 and September 30, 2011, and for the period from August 1, 2005 (inception) through September 30, 2012, and (v) Notes to Condensed Financial Statements.