Nile Therapeutics, Inc.
Form 424B5
April 22, 2010

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-165167

Prospectus Supplement
(To Prospectus dated March 12, 2010)

6,500,000 Units

Common Stock
Warrants

We are offering 6,500,000 units of our securities pursuant to this prospectus supplement and the accompanying prospectus, consisting of an aggregate of 6,500,000 shares of our common stock and warrants to purchase an aggregate of 1,950,000 shares of our common stock. Each unit consists of one share of common stock and 0.30 warrants to purchase common stock. Each whole warrant represents the right to purchase one share of our common stock at an exercise price of $0.94 per share. No fractional warrants will be issued. The units will separate immediately and the common stock and warrants will be issued separately. There will be no market for the units. Each unit will be sold at a purchase price of $0.70.

Our common stock is listed on the Nasdaq Capital Market under the symbol NLTX. On April 21, 2010, the last reported sale price of our common stock on the Nasdaq Capital Market was $0.86 per share. Currently, no public market exists for the warrants offered hereby. The warrants have been approved for listing on the Nasdaq Capital Market under the symbol NLTXW. The warrants will begin trading on or promptly after the date of this prospectus supplement.

Investing in our securities involves a high degree of risk.
See Risk Factors beginning on page S-6 of this prospectus supplement.

	Per Unit	Total
Public offering price	$ 0.70	$ 4,550,000
Underwriting discounts and commissions(1)	$ 0.063	$ 409,500
Proceeds, before expenses, to us	$ 0.637	$ 4,140,500

(1) Does not include a non-accountable expense allowance in the amount of 1% of the gross proceeds of the offering, excluding any over-allotment proceeds. See Underwriting beginning on page S-37 of this prospectus supplement.

We have granted the underwriters a 45-day option to purchase up to an additional 975,000 units from us on the same terms and conditions set forth above.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or accurate. Any representation to the contrary is a criminal offense.

Delivery of the common stock and warrants to purchase common stock is expected to be made on or about April 27, 2010.

As of March 2, 2010, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $25,969,569, which is based on 27,085,824 shares of outstanding common stock, of which 21,641,308 shares are held by non-affiliates, and a per share price of $1.20 based on the closing sale price of our common stock on March 2, 2010. As of the date of this prospectus supplement, we have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar months that ends on the date of this prospectus supplement.

Maxim Group LLC **Ladenburg Thalmann & Co. Inc.**

The date of this prospectus supplement is April 21, 2010

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NILE THERAPEUTICS, INC.

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Through and including May 16, 2010 (the 25th day after the date of this prospectus supplement), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This obligation is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

No dealer, salesperson or any other person is authorized to give any information or make any representations in connection with this offering other than those contained in this prospectus supplement and, if given or made, the information or representations must not be relied upon as having been authorized by us. This prospectus supplement does not constitute an offer to sell or a solicitation of an offer to buy any security other than the securities offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any securities by anyone in any jurisdiction in which the offer of solicitation is not authorized or is unlawful.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is the prospectus supplement, which describes the terms of this offering of our common stock and warrants. The second part is the accompanying prospectus, which provides more general information. Generally, when we refer to the prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, the information in this prospectus supplement shall control. This prospectus supplement contains information about the securities offered in this offering and may add, update or change information in the accompanying prospectus. Before you invest in our securities, you should carefully read this prospectus supplement, along with the accompanying prospectus, in addition to the information contained in the documents we refer to under the heading Incorporation of Certain Information by Reference in this prospectus supplement.

You should rely only on the information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not authorized any person, including any salesman or broker, to provide information or represent anything other than that provided in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with different information. You must not rely on any unauthorized information or representations. We are not making an offer in any jurisdiction or under any circumstances where the offer is not permitted. You should assume that the information in this prospectus supplement and the accompanying prospectus is accurate only as of the date on its cover page and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference.

In this prospectus supplement and the accompanying prospectus, the terms Nile, we, us and our refer to Nile Therapeutics, Inc., a Delaware corporation.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information you should consider before investing in our securities. We urge you to read this entire prospectus supplement and the accompanying prospectus carefully, especially the risks of investing in this offering that we discuss under Risk Factors in this prospectus supplement, as well as the documents identified under Incorporation of Certain Information by Reference in the accompanying prospectus.

Nile Therapeutics, Inc.

Overview

We are a development stage, biopharmaceutical company developing innovative products for the treatment of cardiovascular and renal diseases, with an initial focus on heart failure. We currently have two drug candidates in development, CD-NP and CU-NP. We are focused primarily on the development of CD-NP, our lead drug candidate, which we are currently evaluating in a Phase II clinical trial in patients with acute decompensated heart failure, or ADHF, an acute exacerbation of chronic heart failure. Using the net proceeds from this offering, we expect to complete this initial Phase II trial and have complete data from the trial by the end of 2010.

We hold exclusive, worldwide rights to several patents and patent applications relating to CD-NP and CU-NP pursuant to separate license agreements entered into in January 2006 and June 2008, respectively, between us and the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, which is a part of the Mayo Clinic.

Our Product Candidates

CD-NP

Our lead product candidate CD-NP was designed by scientists at the Mayo Clinic s cardio-renal research laboratories and is in a class of compounds known as natriuretic peptides. Existing therapies for ADHF, which include other natriuretic peptide compounds, have been associated with favorable pharmacologic effects, but have also been associated with abnormally low blood pressure, known as hypotension, and decreased renal function, which limit their utility in clinical practice. CD-NP was designed to preserve the favorable effects of current therapies while eliminating or reducing the hypotensive response, and enhancing or preserving renal function. Results from our preclinical animal studies and early clinical trial data have supported this design hypothesis. In addition to ADHF, based on these preclinical and clinical data, we believe CD-NP has the potential to address additional cardiovascular indications, including chronic heart failure and acute myocardial infarction (heart attacks), as well as renal indications, including renal protection during cardiopulmonary bypass surgery and contrast induced nephropathy, a kidney disease caused by the use of iodine-based dye used in diagnostic imaging and interventional procedures.

We are currently evaluating CD-NP in a single-blind, placebo-controlled Phase II clinical trial designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in hospitalized patients with ADHF and impaired renal function. The purpose of the study, which was initiated in July 2009, is to determine a safe and tolerable dose range of CD-NP that can be used in ADHF patients in the acute setting in combination with the standard of care. The study also contains several exploratory efficacy endpoints to provide insight into the potential

for CD-NP to preserve or enhance renal function in ADHF patients. We anticipate enrolling a total of approximately 75 patients in this Phase II clinical trial. As of March 1, 2010, we have completed dosing 30 subjects in the study.

Interim top-line safety data from the ongoing Phase II study suggests that CD-NP is well-tolerated at dose levels of 1.25 and 2.5 ng/kg/min. In addition to these dose levels, we expect to enroll patient cohorts at increasing doses of CD-NP in this clinical trial. Following analysis of the data from this Phase II study, and subject to what such data indicate, we expect to initiate, either independently or with a development partner, a second larger Phase II dose-ranging, placebo-controlled, double-blind study in ADHF patients with impaired renal function.

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We anticipate that the proceeds from this offering will provide sufficient capital to complete our ongoing Phase II clinical trial and to process and analyze its data. However, we will need substantial additional capital in order to fund the continued development of CD-NP for the treatment of ADHF, particularly if we continue development independently. If the results of our current Phase II trial do not support pursuing further development of CD-NP for the treatment of ADHF, then we may consider development of CD-NP in other indications, including other cardiovascular or renal diseases or conditions. In that case, we will still require substantial additional capital to fund any research and development in such other indications.

CU-NP

CU-NP is also a natriuretic peptide that was designed by scientists at the Mayo Clinic. We are currently evaluating CU-NP in preclinical studies for potential treatment of a number of cardiovascular and renal diseases.

Heart Failure Background

According to the American Heart Association, heart failure is the fastest-growing clinical cardiac disease in the United States, affecting over 5 million Americans. Patients with ADHF are admitted to the hospital over 1 million times per year in the U.S., a rate that has nearly doubled from 15 years ago. Heart failure is the most frequent cause of hospital admission in the U.S. for patients older than 65 years, generating annual inpatient costs of more than $33 billion. We believe that approval of a novel agent with safety and efficacy improvements over existing therapies could potentially satisfy a significant unmet medical need and expand the market for heart failure treatments.

Heart failure, a condition that often follows a heart attack, occurs when the heart cannot pump blood to the body as quickly as needed. When blood returns to the heart faster than the heart can eject it, the system behind the heart becomes congested. Decreased blood flow to organs, such as the kidneys, also causes the body to retain more fluid, further complicating the problem. As a result, heart failure can often cause damage to the kidneys and other organs, which in turn worsens the condition of the heart. ADHF reflects an acute exacerbation of heart failure.

Patients with heart failure are currently treated with a combination of drugs in an attempt to improve cardiac output and reverse fluid overload. Diuretics, such as furosemide (also known by the brand name Lasix®), are used as a first-line treatment to relieve the symptoms of ADHF patients by helping to remove excess fluid from the body, which then helps to increase cardiac output. However, some studies have correlated high doses of intravenous furosemide with a decreased kidney function and some patients can become resistant to the effects of furosemide. Second-line treatments are often designed to only treat symptoms, and can come at the cost of an increased mortality rate. Despite aggressive therapy, one in three ADHF patients die of the disease within a year of diagnosis, reflecting a substantial need for novel treatments.

Corporate Information

We were originally incorporated under Delaware law in August 2005 under the name Nile Pharmaceuticals, Inc., and we changed our name to Nile Therapeutics, Inc. in January 2007. On September 17, 2007, we were acquired by SMI Products, Inc., or SMI, which was then a public shell company, in a reverse merger transaction whereby a wholly-owned subsidiary of SMI merged with and into Nile Therapeutics, with Nile Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of SMI. In accordance with the terms of this transaction, the stockholders of Nile Therapeutics exchanged all of their shares of Nile Therapeutics common stock for shares of SMI common stock, which immediately following the transaction represented approximately 95 percent of the issued and

outstanding common stock of SMI. Upon completion of the merger, the sole officer and director of SMI resigned and was replaced by the officers and directors of Nile Therapeutics. Additionally, following the merger, Nile Therapeutics, or Old Nile, was merged into SMI, and SMI changed its name to Nile Therapeutics, Inc. and adopted the business plan of Old Nile.

Our executive offices are located at 4 West 4th Avenue, Suite 400, San Mateo, California 94402. Our telephone number is (650) 458-2670, and our Internet address is *www.nilethera.com*. We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus or part of any prospectus supplement.

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The Offering

Securities offered by us

6,500,000 units, consisting of an aggregate of 6,500,000 shares of our common stock and warrants to purchase an aggregate of 1,950,000 shares of our common stock. Each unit consists of one share of common stock and 0.30 tradable warrants to purchase common stock. Each warrant will represent the right to purchase one share of our common stock. No fractional warrants will be issued. The units will separate immediately and the common stock and warrants will be issued separately. There will be no market for the units.

Common stock to be outstanding after this offering

33,585,824 shares (assuming none of the warrants issued in this offering are exercised)

Terms of the warrants offered by us

Each warrant will be exercisable during the period commencing on the date of original issuance and ending five years thereafter at an exercise price of $0.94 per share of common stock. See Description of the Securities We Are Offering beginning on page S-32. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants.

Redemption of warrants

In the event the closing sale price of our common stock is at least $3.00 per share for any 20 trading days within a 30 consecutive trading day period, we may call the warrants for redemption, at a redemption price of $0.01 per warrant, by providing at least 30 days notice to each warrant holder. Holders of the warrants will be entitled to exercise the warrants prior to the date scheduled for redemption, but there can be no assurance that the price of our common stock will exceed the call price or the warrant exercise price after the redemption call is made.

Use of proceeds

We intend to use the net proceeds from this offering to fund the completion of our ongoing Phase II clinical trial of CD-NP, and for general corporate purposes and working capital. However, we will need substantial additional capital to fund the development of CD-NP in ADHF or other indications beyond the completion of the ongoing Phase II clinical trial. See Use of Proceeds beginning on page S-29.

Market for our securities

Our common stock is listed for trading on the Nasdaq Capital Market under the symbol NLTX. The warrants have been approved for listing on the Nasdaq Capital Market under the symbol NLTXW.

Risk factors

This investment involves a high degree of risk. See Risk Factors beginning on page S-6 of this prospectus supplement as well as the other information included in or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should consider carefully before making an investment decision.

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The number of shares of our common stock to be outstanding after the offering is based on 27,085,824 shares outstanding as of March 31, 2010, and does not include:

4,901,499 shares of common stock issuable upon the exercise of outstanding stock options, with a weighted average exercise price of $2.29 per share;
969,902 shares of common stock available for future issuance under our Amended & Restated 2005 Stock Option Plan;
3,279,984 shares of common stock issuable upon the exercise of outstanding warrants, with a weighted average exercise price of $1.94 per share;
1,950,000 shares of common stock issuable upon exercise of the warrants offered hereby; and
exercise of the underwriters over-allotment option.

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Summary Financial Data

We derived the following information from our audited financial statements as of and for the years ended December 31, 2009, 2008 and 2007 and for the cumulative period from August 1, 2005 (inception) to December 31, 2009, which financial statements are included in our Annual Reports on Form 10-K for each of the years ended December 31, 2008 and 2009 that we filed with the SEC. The following information should be read in conjunction with our financial statements and related notes incorporated by reference in the accompanying prospectus, and our historical financial statements and related notes contained in our annual reports and quarterly reports.

	Year Ended December 31,			Period from August 1, 2005 (inception) to December 31, 2009
	2009	2008	2007	
Statement of Operations Data:				
Grant income	$	$	$101,400	$482,235
Operating expenses:				
Research and development	4,466,536	9,477,823	5,124,292	21,778,056
General and administrative	3,417,174	3,922,164	4,477,567	11,996,762
Total operating expenses	7,883,710	13,399,987	9,601,859	33,774,818
Total other income (expense)	11,413	268,391	(802,336)	(606,120)
Net loss	(7,872,297)	(13,131,596)	(10,302,795)	(33,898,703)
Net loss per share, basic and diluted	$(0.31)	$(0.54)	$(0.61)	
Weighted average shares used in computing net loss per share, basic and diluted	25,466,655	24,126,398	16,942,142	

	As of December 31, 2009	
	Actual	As Adjusted[(1)]
Balance Sheet Data:		
Cash and cash equivalents	$3,175,718	$7,170,718
Total current assets	3,433,450	7,428,450
Total assets	3,619,704	7,614,704
Total current liabilities	637,554	637,554
Deficit accumulated during the development stage	(33,898,703)	(33,898,703)
Total stockholders equity	2,982,150	6,977,150

(1) On an as adjusted basis to reflect the sale of 6,500,000 units in this offering at a public offering price of $0.70 per unit, after deducting the underwriting discounts, commissions and estimated offering expenses payable by us.

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RISK FACTORS

An investment in our securities involves a high degree of risk. In considering whether to purchase the securities offered by this prospectus supplement, you should carefully consider all of the information we have included or incorporated by reference in this prospectus supplement and the accompanying prospectus. In particular, you should carefully consider the following risk factors and the factors listed in Cautionary Note Regarding Forward-Looking Statements, as well as those incorporated by reference into this prospectus supplement and the accompanying prospectus from the reports we file with the Securities and Exchange Commission, or SEC. You should carefully review all of the information in this prospectus supplement and the accompanying prospectus about these securities.

Risks Relating to Our Business

Our business is substantially dependent on the results of our ongoing Phase II study of CD-NP for the treatment of ADHF and our ability to fund, either alone or with a strategic partner, its further development. If the results of this trial do not support further development of CD-NP in ADHF, our business and future prospects would be materially and adversely affected.

Nearly all of our current human and financial resources are focused on the development of CD-NP, our lead product candidate and our only product candidate in clinical development. In July 2009, we commenced a Phase II clinical trial of CD-NP in patients with ADHF and renal function insufficiency. The purpose of the study is to determine a safe and tolerable dose range of CD-NP that can be used in ADHF patients in the acute setting in combination with the standard of care. The study also contains several exploratory efficacy endpoints to provide insight into the potential for CD-NP to preserve or enhance renal function in acute heart failure patients. If the results of the Phase II trial do not support further development of CD-NP in the ADHF setting, our business and future prospects, as well as the value of our common stock, would be materially and adversely affected.

If the results of the Phase II study support further development of CD-NP for the treatment of ADHF, then we plan to either collaborate with a strategic partner to continue further development of CD-NP or undertake such further development on our own. If we undertake the further development of CD-NP for the treatment of ADHF on our own, then we will require substantial additional capital to fund such further activities and there can be no assurance that such additional capital would be available to us. Further, if the results of the ongoing Phase II trial do not support further development in the ADHF setting, we may choose to pursue development of CD-NP for the treatment of other cardiovascular or renal indications. However, we would also require substantial additional capital beyond the proceeds from this offering in order to fund such other development. If we are unable to identify and secure a partner to continue the further development of CD-NP or obtain the additional funds required to fund such development on our own, our business would be substantially and adversely affected and we would be forced to significantly curtail or even cease our operations, in which case you will lose your entire investment.

Even following completion of this offering, we need substantial additional funding before we can complete the development of our product candidates. If we are unable to raise additional capital beyond the proceeds from this offering, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue to develop CD-NP, our lead product candidate, and initiate

clinical development of CU-NP, our second product candidate. In addition, our expenses could increase beyond expectations if the U.S. Food and Drug Administration, or FDA, requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing to fund the research and development of our product candidates. We have not generated any product revenues, and do not expect to generate any revenues until, and only if, we receive approval to sell our drug candidates from the FDA and other regulatory authorities for our product candidates. As of December 31, 2009, we had cash and cash equivalents totaling $3.2 million. During the fiscal year ended December 31, 2009, we used net cash totaling $5.8 million in operating activities. We expect our

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negative cash flows from operations to continue for the foreseeable future and beyond potential regulatory approval and any product launch. Based on our current development plans, including our ongoing Phase II clinical trial of CD-NP for the treatment of ADHF, we anticipate that the net proceeds from this offering will be sufficient to complete the study activities and analyze the results, which we expect to be completed by the end of 2010. However, if the results from our current Phase II clinical trial are sufficient to support further clinical testing of CD-NP in the ADHF setting, then we will need substantial additional capital in order to initiate and fund the next clinical study of CD-NP, which we anticipate would be a Phase IIb clinical trial.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. In addition, we could be forced to discontinue product development and reduce or forego attractive business opportunities. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our forecasts regarding our beliefs of the sufficiency of our financial resources to support our operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this Risk Factors section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, cost and results of our research and development activities, especially our ongoing Phase II clinical trial of CD-NP;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We are largely dependent on the viability of CD-NP, our lead product candidate, and we cannot be certain it will receive regulatory approval to be commercialized.

We will need FDA approval to market and sell CD-NP in the United States 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

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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.

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, and will have a material and adverse impact on our business.

We are substantially dependent on our relationship with the Mayo Foundation, from which we license the rights to both of our CD-NP and CU-NP drug candidates. If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our drug candidates.

Our rights to our CD-NP and CU-NP drug candidates are both derived from separate license agreements between us and the Mayo Foundation. Our business depends substantially on these agreements to maintain the intellectual property rights to both our product candidates. These license agreements require us to perform certain obligations that affect our rights under these licensing agreements, including making cash payments upon the achievement of certain milestones relating to the development of each product candidate. Both 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. If we fail to comply with our obligations in our license agreements with the Mayo Foundation, we could lose important patent and other intellectual property rights which are critical to our business.

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 product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

Each of our product candidates is in an early stage of development.

Each of our two product candidates, CD-NP and CU-NP, is in an early stage of development and requires extensive clinical testing before it will be approved by the FDA or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. We cannot predict with any certainty the results of such clinical testing, including the results of our ongoing Phase II clinical trial of CD-NP in ADHF. We cannot predict with any certainty if, or when, we might commence any such clinical trials or whether such trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agency.

Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern.

In their report accompanying our audited financial statements, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern. A going concern opinion could impair our ability to finance our operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend, in large part, on our ability to generate positive cash flow from operations and obtain additional

financing if necessary, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

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We have a limited operating history upon which to base an investment decision, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this prospectus:

the need to obtain regulatory approval of our two product candidates, CD-NP and CU-NP;
delays in the commencement, enrollment, and timing of clinical testing;
the success of our clinical trials through all phases of clinical development;
the success of clinical trials of our CD-NP and CU-NP product candidates or future product candidates;
any delays in regulatory review and approval of our product candidates in clinical development;
our ability to receive regulatory approval or commercialize our products within and outside the United States;
potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
regulatory difficulties relating to products that have already received regulatory approval;
market acceptance of our product candidates;
our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
competition from existing products or new products that may emerge;
the impact of competition in the market in which we compete on the commercialization of CD-NP and CU-NP;
guidelines and recommendations of therapies published by various organizations;
the ability of patients to obtain coverage of or sufficient reimbursement for our products;
our ability to maintain adequate insurance policies;
our dependency on third parties to formulate and manufacture our product candidates;
our ability to establish or maintain collaborations, licensing or other arrangements;
our ability and third parties abilities to protect intellectual property rights;
costs related to and outcomes of potential intellectual property litigation;
compliance with obligations under intellectual property licenses with third parties;
our ability to adequately support future growth;
our ability to attract and retain key personnel to manage our business effectively; and
the level of experience in running a public company of our senior management who are relatively new to their current roles as managers of a public company.

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We have a history of net losses, expect to continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

For the years ended December 31, 2009 and 2008, respectively, we had a net loss of $7.9 million and $13.1 million. Since our inception on August 1, 2005, through December 31, 2009, we have accumulated a deficit of $33.9 million and have stockholders equity of $3.0 million. We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. 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;
implement additional internal systems and infrastructure; and
hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders equity and working capital. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth, if any, of our revenues. Revenues from potential strategic partnerships are uncertain because we may not enter into any strategic partnerships. If we are unable to develop and commercialize one or more of our product candidates, or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

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 and Joshua A. Kazam, each of whom are currently directors of our company, and David M. Tanen, a co-founder, director and secretary of our company until September 2009, are the managing members of Two River Consulting, LLC, or Two River. Since June 2009, Mr. Kazam has also served as our President and Chief Executive Officer. In July 2009, we entered into a services agreement with Two River pursuant to which it performs various management, clinical development, operational and administrative activities and services for us. As consideration for these services, we pay Two River a monthly cash fee of $65,000. In addition, upon entering into the services agreement, we issued to designees of Two River (excluding Dr. Belldegrun and Messrs. Kazam and Tanen) stock options to purchase an aggregate of 750,000 shares of our common stock at an exercise price of $0.89 per share. The right to purchase the shares subject to the option vests and becomes exercisable in three installments, the first of which, relating to 187,500 shares, was immediately exercisable upon issuance. A second installment, relating to a total of up to 375,000 shares, was scheduled to vest in its entirety if we, with Two River s services, completed specified clinical development milestones relating to our Phase II clinical trial of CD-NP by January 15, 2010; provided that the services agreement provided that the number of shares that may vest and become exercisable would decrease on a

monthly basis over a five-month period following January 15, 2010. On February 15, 2010, this milestone was achieved, resulting in the vesting of a total of 318,750 shares subject to the second milestone. The third installment, relating to a total of up to 187,500 shares, will vest in its entirety if Two River delivers to us specified data and other written materials relating to the Phase II clinical trial of CD-NP within 90 days

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of completion of the patient enrollment of that study; provided, that the number of shares that will become exercisable in connection with the third installment will decrease on a pro rata basis until the 150th day following completion of patient enrollment, at which time 50% of the shares subject to the third installment will vest, and after 150 days none of the shares subject to the third installment will vest. Each of Messrs. Kazam and Tanen, as well as Peter M. Kash, the chairman of our Board of Directors, are also officers and directors of Riverbank Capital Securities, Inc., or Riverbank, a registered broker-dealer, which served as placement agent in connection with our July 2009 private placement. Scott L. Navins, the Financial and Operations Principal of Riverbank, 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 Two River 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 Two River 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 Two River in the future will be made available to us. In addition, certain of our 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 may not be able to manage our growth.

Should we achieve our near-term milestones, such as completion of our ongoing Phase II clinical trial of CD-NP with positive data, of which no assurance can be given, our long-term viability 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.

We are substantially dependent on the services of Two River and other consultants.

We have only two employees Daron Evans, our Chief Financial Officer, and Hsiao Lieu, our Vice President of Clinical Development. We currently rely heavily on Two River to render various other management, clinical development, regulatory, operational 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.

Our CEO provides his services on a part-time basis and significant other services are currently being rendered by outside consultants. 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 Two River to provide personnel to perform a variety of management, clinical development 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. In addition, Joshua Kazam, our current President and Chief Executive Officer, provides his services to us on a part-time, non-employee

basis. As we further the development of our product candidates, we intend to hire a full-time chief executive officer and other employees to perform the services currently being rendered by Two River. 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

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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 face potential product liability exposure, and if claims are brought against us or if we are found liable, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

withdrawal of clinical trial participants;
termination of clinical trial sites or entire trial programs;
costs of related litigation;
substantial monetary awards to patients or other claimants;
decreased demand for our product candidates;
impairment of our business reputation;
loss of revenues; and
the inability to commercialize our product candidates.

We have obtained product liability insurance coverage for our clinical trials, both foreign and domestically. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We are controlled by current directors, officers, and principal stockholders.

Our directors, officers, and principal stockholders beneficially own approximately 36% of our outstanding voting securities. Accordingly, our executive officers, directors, and principal stockholders 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.

We are required to implement additional 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 will allow our management to report on, and our independent registered public accounting firm to attest to, our internal control over financial reporting when required to do so under Section 404 of the Sarbanes-Oxley Act of 2002. Additionally, we periodically review the effectiveness of our internal controls and procedures with a continuous improvement philosophy.

As a company with limited capital and human resources, we anticipate that more of management s time and attention will be diverted from our business to ensure compliance with these regulatory requirements than would be the case with a company that has well established controls and procedures. This diversion of management s time and attention may have a material adverse effect on our business, financial condition and results of operations.

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In the event we identify significant deficiencies or material weaknesses in our internal control over financial reporting that we cannot remediate in a timely manner, or if we are unable to receive a positive attestation from our independent registered public accounting firm with respect to our internal control over financial reporting when we are required to do so, 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 ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal control 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 affect 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. 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.

Recent turmoil in the financial markets and the global recession has adversely affected and may continue to adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2010. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished expectations for western and emerging economies. In the second half of 2008, added concerns fueled by the U.S. government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government financial assistance to American International Group Inc., Citibank, Bank of America and other federal government interventions in the U.S. financial system lead to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have lead to a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business consumer spending may adversely affect our liquidity and financial condition, including our ability to refinance any maturing liabilities and access the capital markets to meet liquidity needs. If the conditions in the U.S. and world economic markets remain uncertain or continue to be volatile, or if they deteriorate further, our industry and business may be adversely affected.

Risks Relating to the Clinical Testing, Regulatory Approval, Manufacturing and Commercialization of Our Product Candidates

Delays in the commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement, enrollment, and completion of clinical testing could also significantly affect our product development costs. We do not know whether our ongoing Phase II clinical trial of CD-NP will be completed on schedule or at all. Thereafter, subject to the results of our current Phase II trial, we do not know whether further planned clinical trials for CD-NP will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies.

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The commencement, enrollment, and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining regulatory approval to commence a clinical trial;

obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;

recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;

retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;

maintaining and supplying clinical trial material on a timely basis;

complying with design protocols of any applicable special protocol assessment we receive from the FDA; and

collecting, analyzing and reporting final data from the clinical trials.

In addition, a clinical trial may be suspended or terminated by us, the FDA, or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unexpected delays in approvals of protocol amendments by regulatory authorities;

unforeseen safety issues or any determination that a trial presents unacceptable health risks;

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays; or

requirements to conduct additional trials and studies, and increased expenses associated with the services of our CROs and other third parties.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, particularly for our CD-NP and CU-NP product candidates, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. Based upon our discussions with the FDA, we intend to conduct clinical programs for each of our CD-NP and CU-NP product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different than those indications for which we sought approval.

Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of

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regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage.

Any 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.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products or product candidates.

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potentially commercialization. We intend to enter into potential strategic partnerships with third parties to develop and commercialize our product candidates that are intended for larger markets, and we may enter into strategic partnerships for product candidates that are targeted toward specialty markets. We face significant competition in seeking appropriate strategic partners, and these potential strategic partnerships can be intricate and time consuming to negotiate and document. In addition, the early development stage of our product candidates may make it more difficult for us to identify and secure a strategic partner because of the additional risks inherent in early stage technologies. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any potential strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

If we enter into any strategic partnerships with pharmaceutical or biotechnology companies we will be subject to a number of risks, including:

we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;

disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management s attention and consumes resources;

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strategic partners may experience financial difficulties;
strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
business combinations or significant changes in a strategic partner s business strategy may also adversely affect a strategic partner s willingness or ability to complete its obligations under any arrangement; and
strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

As the results of earlier clinical trials are not necessarily predictive of future results, CD-NP, CU-NP or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Even if our clinical trials are completed as planned, including our ongoing Phase II clinical trial of CD-NP, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials does not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after seeing promising results in earlier clinical trials.

Our clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date involve a small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, Phase III or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

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

Our product development efforts focus on novel alternative technologies and therapeutic approaches 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.

Our drug development programs depend upon third-party researchers who are outside our control.

We will 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 collaborators 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.

We rely exclusively on third parties to formulate and manufacture our product candidates.

We have no 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

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candidates. We currently, and intend in the future to, 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 supplies of our drug candidates. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

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