SYNERGY PHARMACEUTICALS, INC.
Form 424B5
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Use these links to rapidly review the document
TABLE OF CONTENTS
Table of Contents

Table of Contents

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Registration No. 333-163316

PROSPECTUS SUPPLEMENT
(To The Prospectus dated December 10, 2009)

273,824 Units

Synergy Pharmaceuticals, Inc.

Units Consisting of One Share of Common and One Warrant to Purchase 0.5 Shares of Common Stock

We are offering up to an aggregate 273,824 units, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock (and the shares of common stock issuable from time to time upon exercise of the offered warrants) pursuant to this prospectus supplement and the accompanying prospectus. The purchase price for each unit is $2.125. Each warrant will have an exercise price of $2.75 per share, will be exercisable immediately and will expire five years from the date of issuance. Units will not be issued or certificated. The shares of common stock and the warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

Our common stock is presently quoted on the OTC QB under the symbol "SGYP." There is no established public trading market for the warrants and we do not expect a market to develop. On October 13, 2011, the last reported sale price of our common stock on the OTC QB was $2.25 per share.

Our business and an investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page S-5 of this prospectus supplement and on page 4 of the accompanying prospectus.

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 complete. Any representation to the contrary is a criminal offense.

	Per Unit	*Total*
Public offering price	**$ 2.125**	**$ 581,876**

We are offering these units on a best efforts basis. We estimate the total expenses of this offering will be approximately $56,550, including up to $46,550 of U.S. broker-dealer fees, assuming the maximum offering amount is sold. See "Plan of Distribution." Because there is no minimum offering amount required as a condition to closing in this offering, the actual offering amount and net proceeds to us, if any, in this offering may be substantially less than the total maximum offering amount set forth above. We are not required to sell any specific number or dollar amount of the units offered in this offering, but we will use our commercially reasonable efforts to arrange for the sale of all of the units offered. We anticipate that delivery of the units will take place as soon as practicable upon completion of the customary closing conditions set forth in the securities purchase agreement.

Prospectus supplement dated October 14, 2011

Table of Contents

TABLE OF CONTENTS

Prospectus Supplement

	Page
About this Prospectus Supplement	ii
Cautionary Statement Regarding Forward-Looking Statements	iii
Prospectus Supplement Summary	S-1
Risk Factors	S-5
Use of Proceeds	S-29
Dividend Policy	S-30
Dilution	S-31
Description of the Securities We Are Offering	S-32
Plan of Distribution	S-33
Experts	S-34
Where You Can Find More Information	S-34
Incorporation of Documents By Reference	S-35

Prospectus

	Page
About this Prospectus	2
Our Business	2
Risk Factors	4
Disclosure Regarding Forward-Looking Statements	17
Use of Proceeds	17
The Securities We May Offer	17
Description of Capital Stock	18
Description of Warrants	20
Description of Units	22
Plan of Distribution	23
Legal Matters	25
Experts	25
Where You Can Find More Information	25
Incorporation of Documents By Reference	26

Table of Contents

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus, gives more general information about securities we may offer from time to time, some of which does not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined together with all documents incorporated by reference. If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference into this prospectus supplement or the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement. You should rely only on the information contained in or incorporated by reference into this prospectus supplement or contained in or incorporated by reference into the accompanying prospectus to which we have referred you. We have not authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in, or incorporated by reference into, this prospectus supplement and contained in, or incorporated by reference into, the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of securities. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions "Where You Can Find More Information" and "Incorporation of Documents by Reference" in this prospectus supplement and in the accompanying prospectus.

We are offering to sell, and are seeking offers to buy, the units only in jurisdictions where such offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the units in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about and observe any restrictions relating to the offering of the units and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and accompanying prospectus, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These statements include, but are not limited to, statements regarding:

- our expectations regarding clinical trials, the timing of clinical results, development timelines and regulatory filings and submissions for our product candidates;
- our plan to initiate an 800 patient, Phase 2/3 90-day repeated-oral-dose, placebo-controlled clinical trial of plecanatide for the treatment of CC in the second half of 2011;
- our plan to initiate a Phase 2b 90-day clinical trial of plecanatide in IBS-C patients in 2012;
- our plan to submit an IND to the FDA to treat UC patients with SP-333 in 2011;
- our intention to initiate a Phase 1 clinical trial of SP-333 for the treatment of UC in 2012;
- our liquidity and our expectations regarding our needs for and ability to raise additional capital; and
- the amount, and our expected uses, of the net proceeds of this offering.

These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown to us that could cause actual results and developments to differ materially from those expressed or implied in such statements, including the risks described under "Risk Factors" in this prospectus supplement, and the other information in this prospectus supplement, the accompanying prospectus and our Annual Report on Form 10-K for the year ended December 31, 2010.

In some cases, you can identify forward-looking statements by terminology, such as "expects," "anticipates," "intends," "estimates," "plans," "believes," "seeks," "may," "should", "could" or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus supplement and the accompanying prospectus.

You should read this prospectus supplement, the accompanying prospectus and the documents that we reference herein and therein, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference is accurate as of their respective dates. Our business, financial condition, results of operations and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless required by law to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this prospectus supplement and the accompanying prospectus, and particularly our forward-looking statements, by these cautionary statements.

Table of Contents

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the "Risk Factors" section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents incorporated by reference into this prospectus supplement and in the accompanying prospectus. Unless we have indicated otherwise or the context otherwise requires, references in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein and therein to the "Company," "we," "us" and "our" refer to Synergy Pharmaceuticals, Inc. and its subsidiaries.

Business Overview

We are a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Our lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic constipation, or CC, and constipation-predominant- irritable bowel syndrome, or IBS-C. CC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CC is primarily characterized by constipation symptoms but a majority of these patients report experiencing bloating and abdominal discomfort as among their most bothersome symptoms. IBS-C is characterized by frequent and recurring abdominal pain and/or discomfort associated with chronic constipation. We are also developing SP-333, our second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis, or UC.

Plecanatide

We are currently developing plecanatide, a synthetic hexadecapeptide designed to mimic the actions of the GI hormone uroguanylin, for the treatment of CC and IBS-C. Plecanatide is an agonist of GC-C receptor.

Plecanatide is covered by a U.S. patent issued on May 9, 2006 with respect to composition of matter that expires on March 25, 2023, subject to possible patent term extension, and a U.S. patent issued on September 21, 2010 with respect to composition of matter that expires on June 9, 2022, subject to possible patent term extension. We have filed patent applications to broaden our patent estate covering GC-C receptor agonists.

14-Day Phase 2a Clinical Trial in CC

Summary. We recently completed a Phase 2a randomized, double-blind, placebo-controlled, 14-day repeat, oral, dose-ranging clinical trial of plecanatide in patients with CC. On October 18, 2010, we presented the results of this clinical trial at the American College of Gastroenterology Annual Scientific Meeting in San Antonio, Texas. This clinical trial enrolled 78 evaluable patients at 14 sites in the United States. The primary objective of this clinical trial was to evaluate the safety of plecanatide in patients with CC. The secondary objectives of this clinical trial were to assess the pharmacokinetic profile of plecanatide and to assess bowel function, including time to first bowel movement, frequency, completeness of evacuation, stool consistency, straining and abdominal discomfort, after treatment with plecanatide.

Clinical Trial Design. In this clinical trial we enrolled patients that met the modified Rome III criteria of CC, a standard patient assessment tool used in the diagnosis of patients with CC. Patients also had to have had a colonoscopy within five years before enrollment with no significant findings, had to be in good health as determined by a physical examination and other standard assessments and had to have reported less than six spontaneous bowel movements, or SBMs, and less than three complete

Table of Contents

SBMs, or CSBMs, in each week during the 14-days before treatment with plecanatide or placebo. SBMs are bowel movements that occur without the use of a laxative, enema or suppository within the preceding 24 hours; and CSBMs are SBMs after which the patient reports a feeling of complete evacuation.

Patients in this clinical trial received placebo or plecanatide once-daily in the morning for 14 consecutive days at oral doses of 0.3 mg, 1.0 mg, 3.0 mg or 9.0 mg, respectively. There were 20 patients per dose level randomized 3:1, with 15 patients in each dose level receiving plecanatide and five patients in each dose level receiving placebo. A safety review was conducted after each dose level before beginning the next higher dose level.

Clinical Trial Results. Plecanatide treatment exhibited a favorable safety profile with no severe adverse events observed, and notably no patients receiving plecanatide reported diarrhea. Ten percent ($^{2}/_{20}$) of patients receiving placebo and 17.2% ($^{10}/_{58}$) of patients receiving plecanatide, respectively, reported adverse events, or AEs, related to treatment and 10% ($^{2}/_{20}$) of patients receiving placebo and 8.6% ($^{5}/_{58}$) of patients receiving plecanatide, respectively, reported GI-related AEs. The majority of AEs were mild to moderate and transient in nature. One patient on placebo was discontinued from the clinical trial due to diarrhea. Additionally, no systemic absorption of plecanatide was detected in patients at any of the dose levels studied.

Patients in all but the 0.3 mg plecanatide dose levels reported significant decreases in time to first bowel movement after dosing as compared to patients receiving placebo. Patients receiving plecanatide also reported increases in the number of SBMs and CSBMs per week, improved stool consistency and reduced straining during bowel movements as compared to pre-treatment levels for each of these measures of bowel function. In addition, a greater percentage of patients in each plecanatide dose level reported improvement in abdominal discomfort, constipation severity and overall relief after treatment as compared to patients receiving placebo.

Development Plan

The next clinical trial of plecanatide to treat chronic idiopathic constipation patients is planned to begin in the second half of 2011 and is being designed as a Phase II/III trial. The trial, a 90-day repeat oral dose ranging, randomized, double-blind, placebo-controlled study, will utilize approximately 800 chronic constipation patients, and will have as its primary objective the measure of CSBMs using a responder analysis. The trial will also evaluate SBMs and daily constipation symptoms including straining, stool consistency, abdominal discomfort, plus impact of plecanatide on disease specific quality of life measures.

We are also preparing to initiate a Phase 2b clinical trial of plecanatide for the treatment of IBS-C in patients during 2012.

SP-333

We are also developing a second generation GC-C receptor analog, SP-333, which is currently in pre-clinical development for the treatment of gastrointestinal inflammatory diseases. SP-333 is a synthetic analog of uroguanylin, a natriuretic hormone which is normally produced in the body's intestinal tract. Deficiency of this hormone is predicted to be one of the primary reasons for the formation of polyps that can lead to colon cancer, as well as debilitating and difficult-to-treat GI inflammatory disorders such as UC and Crohn's disease. We plan to submit an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, to treat UC, and intend to initiate a Phase 1 clinical trial of SP-333 in UC patients during the first half of 2012.

Table of Contents

Corporate Information

We were incorporated in Florida in November 2005 under the name of Pawfect Foods, Inc. On July 14, 2008, we acquired 100% of the common stock of Synergy Pharmaceuticals, Inc., a Delaware corporation, or Synergy DE, under the terms of an Exchange Agreement between us, Callisto Pharmaceuticals, Inc., or Callisto, Synergy-DE and certain other holders of Synergy-DE common stock.

Our principal executive office is located at 420 Lexington Avenue, Suite 1609, New York, New York 10170. Our telephone number is (212) 297-0020 and our website address is www.synergypharma.com. The information on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement or the accompanying prospectus.

Table of Contents

The Offering

Securities offered by us	273,824 units, each consisting of one share of common stock and a warrant to purchase 0.5 shares of common stock.
Common stock to be outstanding after this offering	96,296,174 shares or 96,433,086 shares if the warrants sold in this offering are exercised in full.
Warrants	Warrants to purchase an aggregate of 136,912 shares of common stock will be offered as part of the units being sold in this offering.
Warrant exercise price	The exercise price of the warrants is $2.75.
Warrant exercisability and expiration	The warrants will be exercisable immediately after the original date of issuance and will expire five years thereafter.
Anti-dilution	The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock. Additionally, the exercise price of the warrants is subject to certain adjustments if we issue or sell any additional shares of common stock or common stock equivalents at a price per share less than the exercise price then in effect or without consideration.
Use of proceeds	We intend to use the net proceeds from this offering to fund our research and development activities, including our planned Phase 2/3 clinical trial of plecanatide and our Phase 1 clinical trial of SP-333, and for working capital and other general corporate purposes, and possibly acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated. See "Use of Proceeds" on page S-29.
Risk factors	See "Risk Factors" beginning on page S-5 of this prospectus supplement and other information included or incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before investing in our common stock.
OTC QB Trading symbol	"SGYP"

The information above is based on 96,022,350 shares of common stock outstanding as of October 13, 2011. It does not include:

8,314,077 shares of our common stock issuable upon exercise of outstanding stock options as of October 13, 2011 under our 2008 Equity Compensation Incentive Plan at a weighted average exercise price of $0.51 per share, with 6,685,923 shares remaining available for future grant under that plan;

1,000,000 shares of our common stock available for future grant under our 2009 Directors Stock Option Plan; and

3,588,964 shares of our common stock issuable upon exercise of outstanding warrants as of October 13, 2011 at a weighted average exercise price of $3.03 per share.

Table of Contents

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements and related notes.

Risks Related to Our Business

We are at an early stage of development as a company, currently have no source of revenue and may never become profitable.

We are a development stage biopharmaceutical company. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue. Our ability to generate revenue depends heavily on:

- demonstration in current and future clinical trials that our product candidate, plecanatide for the treatment of GI disorders, is safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, if we do not successfully develop and commercialize plecanatide, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

To date, we have funded our operations primarily from sales of our securities. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future.

As of June 30, 2011, we had an accumulated deficit of $63,400,771. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of plecanatide for the treatment of GI disorders, acquire or license technologies, advance other product candidates into clinical development, including SP-333, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the

Table of Contents

numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

We will need to raise substantial additional capital to fund our operations, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs.

Our operations have consumed $28,833,066 since inception through June 30, 2011. We expect to continue to spend substantial amounts to:

- continue clinical development of plecanatide to treat GI disorders;
- continue development of other product candidates, including SP-333;
- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for plecanatide and other product candidates, including SP-333;
- license or acquire additional technologies;
- launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and
- develop and implement sales, marketing and distribution capabilities.

We will be required to raise additional capital to complete the development and commercialization of our current product candidates and to continue to fund operations at the current cash expenditure levels. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other development activities;
- any future decisions we may make about the scope and prioritization of the programs we pursue;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

general market conditions for offerings from biopharmaceutical companies.

Worldwide economic conditions and the international equity and credit markets have recently significantly deteriorated and may remain depressed for the foreseeable future. These developments could make it more difficult for us to obtain additional equity or credit financing, when needed.

We cannot be certain that funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms,

Table of Contents

we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and/or

- relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

We are largely dependent on the success of our lead product candidate, plecanatide, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.

We currently have no products for sale, and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, for a product candidate from the FDA or the equivalent approval from a foreign regulatory authority. Obtaining FDA approval is a lengthy, expensive and uncertain process. We currently have one lead product candidate, plecanatide for the treatment of GI disorders, and the success of our business currently depends on its successful development, approval and commercialization. This product candidate has not completed the clinical development process; therefore, we have not yet submitted an NDA or foreign equivalent or received marketing approval for this product candidate anywhere in the world.

The clinical development program for plecanatide may not lead to commercial products for a number of reasons, including if we fail to obtain necessary approvals from the FDA or foreign regulatory authorities because our clinical trials fail to demonstrate to their satisfaction that this product candidate is safe and effective. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure or delay in completing clinical trials or obtaining regulatory approval for plecanatide in a timely manner would have a material adverse impact on our business and our stock price.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Table of Contents

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our consolidated financial statements as of December 31, 2010 were prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

variations in the level of expenses related to our development programs;

addition or termination of clinical trials;

any intellectual property infringement lawsuit in which we may become involved;

regulatory developments affecting our product candidates;

our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and

if plecanatide receives regulatory approval, the level of underlying demand for that product and wholesalers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

A substantial amount of our common stock is owned by a single stockholder, and it may therefore be able to substantially control our management and affairs.

Callisto Pharmaceuticals, Inc., or Callisto, owns approximately 46.4% of our outstanding common stock as of October 13, 2011. Therefore, Callisto will be able to have substantial influence over any election of our directors and our operations. It should also be noted that for the most part, authorization to modify our Articles of Incorporation, as amended, requires only majority stockholder consent. Approval to modify our amended and restated By-Laws requires authorization of only a majority of the board of directors. This concentration of ownership could also have the effect of delaying or preventing a change in our control.

Our management overlaps substantially with the management and beneficial owners of our principal stockholder, which may give rise to potential conflicts of interest.

Several of our executive officers and directors are also officers and/or directors of our principal stockholder, Callisto, and certain of such executive officers and directors are, in turn, the principal stockholders of Callisto. Accordingly, there may be inherent, albeit non-specific, potential conflicts involved in the participation by members of each company's management, audit committee, compensation committee, nominating committee and other applicable board committees which will oversee questions of possible conflicts of interest and compensation, notwithstanding an effort to appoint independent directors that do not have these inherent conflicts. In addition, as a matter of

Table of Contents

practicality, efficiency and appropriate accounting, the costs of certain service (including salaries of executive officers) are allocated, which creates inter-company obligations.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

The FDA's expectations for clinical trials may change over time, complicating the process of obtaining evidence to support approval of our product candidates.

In March 2010, the FDA's Center for Drugs Evaluation and Research, or CDER, released a draft guidance entitled: "Irritable Bowel Syndrome Clinical Evaluation of Products for Treatment" to assist the product sponsors developing new drugs for the treatment of IBS. In pertinent part, this document provides recommendations for IBS clinical trial design and endpoints, and describes the need for the future development of patient-reported outcome, or PRO, instruments for use in IBS clinical trials. The clinical trials we have planned for plecanatide are designed to follow the recommendations included in this draft guidance. We cannot predict when the draft guidance will be finalized and, if it is finalized, whether the final version will include the same recommendations, or whether our currently planned clinical trials of plecanatide will meet the final recommendations.

When finalized, the guidance document will represent the FDA's thinking on the clinical evaluation of products for the treatment of IBS. FDA guidance documents, however, do not establish legally

Table of Contents

enforceable requirements, should be viewed only as recommendations, and may be changed at any time. Therefore, even insofar as we intend to follow the recommendations provided in the draft guidance document and the final guidance document when revealed, we cannot be sure that the FDA will accept the results of our clinical research even if such research follows the recommendations in the guidance document.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including

Table of Contents

commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States and we will not generate any revenue.

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data are insufficient to support approval of our product candidates for the claimed intended uses. In addition, even if we obtain approval of an application to market our product candidates, the FDA may subsequently seek to withdraw approval of our NDA if it determines that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, it may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We

Table of Contents

cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidates, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize GI drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If approved and commercialized, plecanatide will compete with at least one currently approved prescription therapy for the treatment of CC and IBS-C, Amitiza. In addition, over-the-counter products are also used to treat certain symptoms of CC and IBS-C. We believe other companies are developing products that will compete with plecanatide should they be approved by the FDA. For example, linaclotide is being developed by Ironwood Pharmaceuticals, Inc. This compound is being co-developed with Forest Laboratories, Inc. and has completed Phase 3 clinical trials for CC and for IBS-C. Another compound, velusetrag, is being developed by Theravance, Inc. and has completed Phase 2 clinical trials for CC. To our knowledge, other potential competitors are in earlier stages of development . If our potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for plecanatide.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to existing GI drugs. If we are unable to compete effectively in the GI drug market and differentiate our products from other marketed GI drugs, we may never generate meaningful revenue.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish this

Table of Contents

sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

We may need others to market and commercialize our product candidates in international markets.

In the future, if appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. Currently, we do not have any plans to enter international markets. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

If the manufacturers upon whom we rely fail to produce plecanatide and our product candidates, including SP-333, in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidates.

We do not currently possess internal manufacturing capacity. We currently utilize the services of contract manufacturers to manufacture our clinical supplies. With respect to the manufacturing of plecanatide, we are currently pursuing long-term commercial supply agreements with multiple manufacturers. Any curtailment in the availability of plecanatide could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations, including good manufacturing practices, or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidates. Peptide manufacturing is a highly specialized manufacturing business. While we believe we will have long term arrangements with a sufficient number of contract manufacturers, if we lose a manufacturer, it would take us a substantial amount of time to identify and develop a relationship, and seek regulatory approval, where necessary, for an alternative manufacturer.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control,

Table of Contents

including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with GMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers of plecanatide and other product candidates, including SP-333, may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any. While we will oversee compliance by our contract manufacturers, ultimately we have no control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of plecanatide or other product candidates is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize plecanatide or other product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of plecanatide or other product candidates, entail higher costs or result in our being unable to effectively commercialize plecanatide or other product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the bulk active pharmaceutical ingredients, or APIs, and

Table of Contents

product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

Demonstration of efficacy;

Changes in the practice guidelines and the standard of care for the targeted indication;

Relative convenience and ease of administration;

The prevalence and severity of any adverse side effects;

Budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

Pricing and cost effectiveness, which may be subject to regulatory control;

Effectiveness of our or any of our partners' sales and marketing strategies;

The product labeling or product insert required by the FDA or regulatory authority in other countries; and

The availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science

Table of Contents

foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed products.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

initiation of investigations by regulators;

substantial monetary awards to patients or other claimants;

distraction of management's attention from our primary business;

product recalls;

loss of revenue; and

the inability to commercialize our product candidates.

We have clinical trial liability insurance with a $5,000,000 aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy liabilities that may arise.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology

companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

Table of Contents

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Plecanatide and other product candidates, including SP-333, would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or GMP, regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;

Table of Contents

impose civil or criminal penalties;

suspend regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to applications filed by us;

impose restrictions on operations, including costly new manufacturing requirements;

seize or detain products or request us to initiate a product recall; or

pursue and obtain an injunction.

Drugs approved to treat IBS have been subject to considerable post-market scrutiny, with consequences up to and including voluntary withdrawal of approved products from the market. This may heighten FDA scrutiny of our product candidates before or following market approval.

Products approved for the treatment of IBS have been subject to considerable post-market scrutiny. For example, in 2007, Novartis voluntarily discontinued marketing Zelnorm (tegaserod), a product approved for the treatment of women with IBS-C, after the FDA found an increased risk of serious cardiovascular events associated with the use of the drug. Earlier, in 2000, Glaxo Wellcome withdrew Lotronex (alosetron), which was approved for women with severe diarrhea-prominent IBS, after the manufacturer received numerous reports of AEs, including ischemic colitis, severely obstructed or ruptured bowel, or death. In 2002, the FDA approved the manufacturer's application to make Lotronex available again, on the condition that the drug only be made available through a restricted marketing program.

Although plecanatide is being investigated for IBS, plecanatide is from a different pharmacologic class than Zelnorm or Lotronex, and would not be expected to share the same clinical risk profile as those agents. Nevertheless, because these products are in the same or related therapeutic classes, it is possible that the FDA will have heightened scrutiny of plecanatide or any other agent under development for IBS. This could delay product approval, increase the cost of our clinical development program, or increase the cost of post-market study commitments for our IBS product candidates, including plecanatide.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval to commercialize them outside of the United States.

In the future, we may seek to commercialize plecanatide and/or other product candidates, including SP-333, in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that plecanatide or other product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of plecanatide or other

Table of Contents

product candidates and have an adverse effect on our products' commercial potential or require costly post-marketing studies.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.

We have agreements with third-party contract research organizations, or CROs, under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or GCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Gary S. Jacob, Ph.D., our President and Chief Executive Officer, Kunwar Shailubhai, Ph.D., our Chief Scientific Officer and Laura Barrow, Pharm.D., our Vice President of Clinical Operations. The loss of services of Dr. Jacob or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 8 full-time and 2 part-time employees as of October 13, 2011. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit,

Table of Contents

maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidates may depend on reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payers pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S.

Table of Contents

and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA. This law will substantially change the way health care is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will be required to provide a 50% discount on branded prescription drugs sold to beneficiaries who fall within the donut hole. Similarly PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also included significant changes to the 340B Drug Pricing Program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare covers and reimburses for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our proposed products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could

Table of Contents

result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Our ability to use our net operating loss carryforwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2010, we had net operating loss carryforwards aggregating approximately $43 million. We have determined that an ownership change occurred as of April 30, 2003 pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. In addition, the shares of our common stock that we issued during the year ended December 31, 2010 have resulted in additional ownership change. As a result of these events, our ability to utilize our net operating loss carry forwards is limited.

In preparing our consolidated financial statements, we identified material weaknesses in our internal control over financial reporting, and our failure to remedy the material weakness identified as of December 31, 2010 and our ineffective disclosure controls and procedures could result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management identified one material weakness in our internal control over financial reporting as of December 31, 2010. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As a result of this material weakness, our management concluded as of December 31, 2010 that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control An Integrated Framework (September 1992).

During the year ended December 31, 2010 we implemented and continue to implement remedial measures designed to address these material weaknesses and the ineffectiveness of our disclosure controls and procedures. If these remedial measures are insufficient to address these material weaknesses and the ineffectiveness of our disclosure controls and procedures, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future and the ineffectiveness of our disclosure controls and procedures continues, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation, and if we gain a listing on the NYSE Amex, our common stock could be delisted from that exchange. Any failure to address the identified material weaknesses or any additional material weaknesses in our internal control or the ineffectiveness of our disclosure controls and procedures could also adversely affect the results of the periodic management evaluations regarding the effectiveness of our internal control over financial reporting and our disclosure controls and procedures that are required to be included in our annual report on Form 10-K. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that the measures we plan to take in the future will remediate the material weaknesses identified or the

Table of Contents

ineffectiveness of our disclosure controls and procedures or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, if we fail to remedy the material weaknesses and other deficiencies in our internal control and accounting procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, if we fail to remedy the material weaknesses and other deficiencies in our internal control and accounting procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent auditors addressing these assessments. We have documented and tested our internal control procedures, and we have identified material weaknesses in our internal control over financial reporting and other deficiencies. These material weaknesses and deficiencies could cause investors to lose confidence in our Company and result in a decline in our stock price and consequently affect our financial condition. We have begun to implement and continue to implement remedial measures designed to address these material weaknesses. In addition, if these remedial measures are insufficient to address these material weaknesses, if additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities.

As of October 13, 2011 we have three issued United States patents. Two of these patents cover the composition-of-matter of plecanatide and were issued on May 9, 2006 and September 21, 2010; they will expire in 2023 and 2022, respectively. The third patent covers the composition-of-matter of SP333 issued on February 1, 2011 and expires in 2028. In addition, we have three issued foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria,

Table of Contents

Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Turkey, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyz Republic, Moldova, Russian Federation, Tajikistan, Turkmenistan, Hong Kong and Japan.

Additionally as of October 13, 2011, we have 11 pending United States patent applications (seven utility and four provisional) and 29 pending foreign patent applications covering various derivatives and analogs of plecanatide and SP-333. We may file additional patent applications and extensions. In April 2010, two parties filed an opposition to our granted European patent with the European Patent Office. We cannot predict the final outcome of the opposition, which is likely to take several years to complete.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our issued patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In

Table of Contents

addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Table of Contents

We have not yet registered trademarks for plecanatide in our potential markets, and failure to secure those registrations could adversely affect our ability to market our product candidate and our business.

We have not yet registered trademarks for plecanatide in any jurisdiction. Our trademark applications in the United States, when filed, and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our product candidates and our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to this Offering

You will experience immediate dilution in the net tangible book value per share of the common stock you purchase.

The public offering price of our common stock is substantially higher than our net tangible book value per share of common stock. Based on the public offering price of $2.125 per unit, investors

Table of Contents

purchasing shares in this offering will, therefore, incur immediate dilution of $2.075 in net tangible book value per share. This dilution figure deducts the estimated discounts and commissions and estimated offering expenses payable from the public offering price.

Because we will have broad discretion and flexibility in how the net proceeds from this offering are used, we may use the net proceeds in ways in which you disagree.

We currently intend to use the net proceeds from this offering to fund our research and development activities, including our planned Phase 2/3 clinical trial of plecanatide and our Phase 1 clinical trial of SP-333, and for working capital and other general corporate purposes, and possibly acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated. See "Use of Proceeds" on page S-29. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

The market price of our common stock may be volatile and adversely affected by several factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- period-to-period fluctuations in our financial results; and
- whether an active trading market in our common stock develops and is maintained.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our capital stock and do not anticipate paying cash dividends on our capital stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common

Table of Contents

stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, including the ending of restriction on resale or the expiration of lock-up agreements such as those entered into in connection with this offering, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and biopharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. 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 and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

There is no public market for the warrants to purchase common stock being sold in this offering.

There is no established public trading market for the warrants being offered in this offering and we do not expect a market to develop. In addition, we do not intend to apply for listing the warrants on any national securities exchange. Without an active market, the liquidity of the warrants will be limited. Further, the existence of the warrants may act to reduce both the trading volume and the trading price of our common stock.

Table of Contents

USE OF PROCEEDS

We estimate that our net proceeds from the sale of the units offered pursuant to this prospectus supplement, will be approximately $525,326 based upon the public offering price of $2.125 per unit and after deducting placement agent fees and the estimated offering expenses that are payable by us. These amounts do not include the proceeds which we may receive in connection with the exercise of the warrants. We cannot predict when or if the warrants will be exercised, and it is possible that the warrants may expire and never be exercised.

We currently intend to use the net proceeds from this offering to fund our research and development activities, including our planned Phase 2/3 clinical trial of plecanatide, our Phase 1 clinical trial of SP-333, for working capital and other general corporate purposes and possibly acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering. Pending any use, as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

Table of Contents

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

Table of Contents

DILUTION

If you purchase our securities in this offering, your interest will be diluted to the extent of the difference between the public offering price per unit and the net tangible book value per share of our common stock after this offering. We calculate net tangible book value per share by dividing our net tangible assets (tangible assets less total liabilities) by the number of shares of our common stock issued and outstanding as of June 30, 2011.

Our pro forma net tangible book value at June 30, 2011 was $(5,440,907), or $(0.06) per share, based on 96,022,350 shares of our common stock outstanding, after giving effect to issuances of common stock from July 1, 2011 through and immediately prior to the date of this offering. After giving effect to the issuance and sale of all the units in this offering at the public offering price of $2.125 per unit, less the estimated offering expenses, our adjusted pro forma net tangible book value at June 30, 2011 would be $4,915,581 or $(0.05) per share. This represents an immediate increase in net tangible book value of $0.01 per share to existing stockholders and an immediate dilution of $2.075 per share to investors in this offering. The following table illustrates this per share dilution:

Public offering price per unit		$ 2.125
Pro forma net tangible book value per share as of June 30, 2011	$ (0.06)	
Increase per share attributable to investors in this offering	$ 0.01	
Adjusted pro forma net tangible book value per share as of June 30, 2011		$ (0.05)
Dilution per share to investors in this offering		$ 2.075

The foregoing illustration does not reflect potential dilution from the exercise of outstanding options or warrants to purchase shares of our common stock.

Table of Contents

DESCRIPTION OF THE SECURITIES WE ARE OFFERING

In this offering, we are offering 273,824 units, consisting of 273,824 shares of common stock and warrants to purchase 136,912 shares of common stock. The common stock and warrants will be sold in units, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock. Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately. The shares of common stock issuable from time to time upon exercise of the warrants, if any, are also being offered pursuant to this prospectus supplement.

Common Stock

A description of the securities we are offering pursuant to this prospectus supplement is set forth hereunder and under the heading "The Securities We May Offer" starting on page 18 of the accompanying prospectus. As of October 13, 2011, we had 96,022,350 shares of common stock outstanding.

Warrants

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the forms of the warrant, which are attached or referenced to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.

Exercisability. The warrants are exercisable beginning on the date of original issuance and at any time up to the date that is five years after such date. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

Exercise Price. The initial exercise price per share of common stock purchasable upon exercise of the warrants is $2.75 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Certain Adjustments. The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock. Additionally, the exercise price of the warrants is subject to certain adjustments if we issue or sell any additional shares of common stock or common stock equivalents at a price per share less than the

Table of Contents

exercise price then in effect, or without consideration, the exercise price then in effect will be adjusted. Notwithstanding the foregoing, there will be no adjustment to the exercise price with respect to the sale or issuance of certain excluded securities.

Transferability. Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

Exchange Listing. There is no established public trading market for the warrants. We do not plan on making an application to list the warrants on any national securities exchange or other nationally recognized trading system.

Fundamental Transaction. If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each, a "Fundamental Transaction," then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

PLAN OF DISTRIBUTION

We intend to enter into securities purchase agreements with investors for the purchase of units in this offering. At the closing, Depository Trust Company will credit the shares to the respective accounts of the investors and we will issue the warrants. We currently anticipate that closing of the sale of the units under this prospectus supplement will take place as soon as practicable upon completion of the closing conditions set forth in the securities purchase agreements. Confirmations and this prospectus supplement and accompanying prospectus will be distributed to all investors who agree to purchase the units, informing investors of the closing date as to these securities.

We have entered into an agreement with Maxim Group LLC, a U.S. broker-dealer to pay placement agent fees in an amount equal to 8% of the gross proceeds from any sales of units by Maxim Group LLC. The estimated offering expenses payable by us, excluding the placement agent fees, are approximately $10,000, which includes legal, accounting and printing costs and various other fees associated with registering and listing the common stock. After deducting placement agent fees and our estimated offering expenses, we expect the net proceeds from this offering, in the event the maximum offering amount is sold, to be approximately $525,326.

Table of Contents

In compliance with the guidelines of the Financial Industry Regulatory Authority ("FINRA"), the maximum consideration or discount to be received by any FINRA member may not exceed 8% of the gross offering proceeds or any other offering in the United States.

We have agreed to indemnify Maxim Group LLC and specified other persons against some civil liabilities, including liabilities under the Securities Act and the Exchange Act.

The form of securities purchase agreement with the purchasers and the form of warrant are included as exhibits to our Current Report on Form 8-K that will be filed with the Securities and Exchange Commission prior to the completion of this offering.

Our common stock is quoted on the OTC Bulletin Board under the symbol "SGYP." The warrants to purchase shares of common stock issued to the investors in this offering are not expected to be eligible for trading on any market.

EXPERTS

The financial statements as of December 31, 2010 and 2009 and for the two years in the period ended December 31, 2010 and the period from November 15, 2005 (inception) to December 31, 2010 and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2010 incorporated by reference into this prospectus supplement have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and the accompanying prospectus are part of the registration statement on Form S-3 we filed with the Securities and Exchange Commission, or SEC, under the Securities Act, and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete, and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus supplement and the accompanying prospectus for a copy of such contract, agreement or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the SEC's public reference room mentioned below, or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

We also maintain a web site at www.synergypharma.com, through which you can access our SEC filings. The information set forth on our web site is not part of this prospectus supplement.

Table of Contents

INCORPORATION OF DOCUMENTS BY REFERENCE

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (unless otherwise noted, the SEC file number for each of the documents listed below is 333-131722):

- our Annual Report on Form 10-K for the year ended December 31, 2010 filed on March 16, 2011.
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 filed on May 10, 2011.
- our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed on August 9, 2011.
- our Current Reports on Form 8-K filed on February 14, 2011, March 10, 2011, May 6, 2011, May 23, 2011, August 3, 2011 and October 6, 2011.
- the description of our Common Stock contained in the registration statement on Form 8-A, filed on August 3, 2011.

In addition, all documents filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the date of this prospectus supplement and before the termination of the offering under this prospectus supplement are deemed to be incorporated by reference into, and to be a part of, this prospectus supplement.

You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

Synergy Pharmaceuticals, Inc.
420 Lexington Avenue
Suite 1609
New York, New York 10170
Attn.: Corporate Secretary
Tel: (212) 297-0020

Table of Contents

SYNERGY PHARMACEUTICALS, INC.

$100,000,000

Common Stock
Preferred Stock
Warrants
Units

We may offer and sell, from time to time in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding $100,000,000. When we decide to sell a particular class or series of securities, we will provide specific terms of the offered securities in a prospectus supplement.

We will provide specific terms of the offerings of our securities in supplements to this prospectus. The prospectus supplement may also add, update or change information in this prospectus. You should read this prospectus and any prospectus supplement, as well as the documents incorporated by reference or deemed to be incorporated by reference into this prospectus, carefully before you invest.

This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement relating to the offered securities.

Our common stock is traded on the OTC Bulletin Board under the symbol "SGYP." On December 4, 2009, the last reported sale price for the common stock was $4.50 per share.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters or through a combination of these methods. See "Plan of Distribution" in this prospectus. We may also describe the plan of distribution for any particular offering of our securities in a prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

Investing in our securities involves various risks. See "Risk Factors" on page 4 for more information on these risks. Additional risks will be described in the related prospectus supplements under the heading "Risk Factors". You should review that section of the related prospectus supplements for a discussion of matters that investors in our securities should consider.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus or any accompanying prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this Prospectus is December 10, 2009.

Table of Contents

TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	2
OUR BUSINESS	2
RISK FACTORS	4
DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS	17
USE OF PROCEEDS	17
THE SECURITIES WE MAY OFFER	17
DESCRIPTION OF CAPITAL STOCK	18
DESCRIPTION OF WARRANTS	20
DESCRIPTION OF UNITS	22
PLAN OF DISTRIBUTION	23
LEGAL MATTERS	25
EXPERTS	25
WHERE YOU CAN FIND MORE INFORMATION	25
INCORPORATION OF DOCUMENTS BY REFERENCE	26

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC") using a "shelf" registration process. Under this shelf registration process, we may offer from time to time securities having an aggregate initial offering price of $100,000,000. Each time we offer securities, we will provide you with a prospectus supplement that describes the specific amounts, prices and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under the caption "Where You Can Find More Information."

This prospectus does not contain all the information provided in the registration statement we filed with the SEC. For further information about us or our securities offered hereby, you should refer to that registration statement, which you can obtain from the SEC as described below under "Where You Can Find More Information."

You should rely only on the information contained or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

We may sell securities through underwriters or dealers, through agents, directly to purchasers or through a combination of these methods. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of securities. The prospectus supplement, which we will provide to you each time we offer securities, will set forth the names of any underwriters, agents or others involved in the sale of securities, and any applicable fee, commission or discount arrangements with them. See "Plan of Distribution."

OUR BUSINESS

Synergy Pharmaceuticals, Inc. is referred to throughout this prospectus as "Synergy," "we" or "us."

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat GI ("GI") disorders and diseases. Our lead drug candidate is SP-304, a guanylyl cyclase C (GC-C) receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C"). On April 2, 2008, we filed an investigational new drug (IND) application with the FDA. On May 2, 2008 we received notice from the FDA that our proposed study was deemed safe to proceed and we initiated a Phase I clinical trial in volunteers on June 4, 2008.

On December 9, 2008, we announced the completion of the Phase I clinical trial of SP-304 in healthy volunteers that was initiated in June 2008. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending dose trial performed in 71 healthy male and female volunteers. The primary objective of the Phase I clinical trial with SP-304 was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers. The clinical data from the SP-304 Phase I healthy volunteer study was included in an abstract presented at the Digestive Disease Week conference held in Chicago IL from May 30 through June 4, 2009. SP-304 was well tolerated at all doses studied (0.1 mg to 48.6 mg) and exhibited pharmacodynamic activity in healthy volunteers with no detectable systemic absorption. These data clearly supported advancing

Table of Contents

SP-304 for further clinical studies in patients with CC and IBS-C. We plan to initiate a Phase IIa 14-day, repeated-oral-dose trial of SP-304 in chronic constipation patients in early 2010.

A practical, efficient and cost effective method for producing SP-304 on a commercial scale is currently being investigated in concert with multiple manufacturing contract research organizations (CRO's). At present, we have about 500 grams of SP-304, produced under current good manufacturing practices ("cGMP"), which are being used for non-clinical work to support further human clinical trials.

SP-304 was developed by our scientists based on structure-function studies performed in-house. A patent covering composition of matter and therapeutic applications of SP-304 was granted by the U.S. Patent and Trademark Office on May 9, 2006.

SP-304 is an analog of uroguanylin, a natural GI hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating GC-C receptors on intestinal cells. The GC-C receptor, promotes fluid and ion transport in the GI tract. Under normal conditions, the receptor is activated by the natural hormones uroguanylin and guanylin. Activation of the receptor leads to the transport of chloride and bicarbonate into the intestine, and water is carried with these ions into the lumen of the intestine, thereby softening stool, and producing other pharmacologic, beneficial effects that could potentially benefit patients with CC and IBS-C

SP-304 has been demonstrated to be superior to uroguanylin in its biological activity, protease stability and pH characteristics. SP-304 acts in an identical manner as the natural hormone as an agonist (i.e. activator) of the GC-C receptor found on the epithelial cells of the colon. Upon activation, the GC-C receptor promotes intracellular synthesis of cyclic guanosine monophosphate ("C-GMP"), which in turn eventually activates the cystic fibrosis transmembrane conductance regulator ("CFTR") within the epithelial cells. Activation of CFTR leads to secretion of salts and water into the intestine, resulting in a liquid and watery intestine content that is more easily transported through the bowel. Recent animal studies performed with SP-304 have demonstrated the drug's potential to enhance intestinal motility.

SP-304 has also undergone pre-clinical animal studies as a treatment for GI inflammation in a collaborative study involving clinical gastroenterologist Dr. Scott Plevy of the University of North Carolina, Chapel Hill, NC. Results from his laboratory showed that SP-304 was efficacious in animal models of ulcerative colitis. A second generation GC-C receptor analog, SP-333, is now in pre-clinical development and we plan to file an IND to treat UC patients in 2010.

Our principal executive office is located at 420 Lexington Avenue, Suite 1609, New York, New York 10170. Our telephone number is (212) 297-0020 and our website address is www.synergybio.net. The information on our website is not incorporated by reference into this prospectus.

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

We Are At An Early Stage Of Development As A Company, Currently Have No Source Of Revenue And May Never Become Profitable.

We are a development stage biopharmaceutical company. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue. Our ability to generate revenue depends heavily on:

- demonstration in Phase IIa, Phase IIb and Phase III clinical trials that our product candidate, SP-304 for the treatment of GI disorders, is safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates will require extensive additional clinical evaluation, regulatory review, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, if we do not successfully develop and commercialize SP-304, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for several years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

We Have Incurred Significant Losses Since Inception And Anticipate That We Will Incur Continued Losses For The Foreseeable Future.

As of December 31, 2008 and September 30, 2009, we had an accumulated deficit of $31,795,441 and $36,978,212, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development, continue our clinical trials of SP-304 for the treatment of GI disorders, acquire or license technologies, advance our other product candidates into clinical development, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we are unable to achieve and then maintain profitability, the market value of our common stock will likely decline.

Table of Contents

We Will Need To Raise Substantial Additional Capital Within The Next Year To Fund Our Operations, And Our Failure To Obtain Funding When Needed May Force Us To Delay, Reduce Or Eliminate Our Product Development Programs Or Collaboration Efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

continue clinical development of SP-304 to treat GI disorders;

continue development of our other product candidates;

finance our general and administrative expenses;

prepare regulatory approval applications and seek approvals for SP-304 and our other product candidates;

license or acquire additional technologies;

launch and commercialize our product candidates, if any such product candidates receive regulatory approval; and

develop and implement sales, marketing and distribution capabilities.

We will be required to raise additional capital within the next year to complete the development and commercialization of our current product candidates and to continue to fund operations at the current cash expenditure levels. Our future funding requirements will depend on many factors, including, but not limited to:

the rate of progress and cost of our clinical trials and other development activities;

any future decisions we may make about the scope and prioritization of the programs we pursue;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the costs and timing of regulatory approval;

the costs of establishing sales, marketing and distribution capabilities;

the effect of competing technological and market developments;

the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

general market conditions for offerings from biopharmaceutical companies.

Worldwide economic conditions and the international equity and credit markets have recently significantly deteriorated and may remain depressed for the foreseeable future. These developments could make it more difficult for us to obtain additional equity or credit financing, when

needed.

We cannot be certain that funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and

Table of Contents

relinquish license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our Independent Registered Public Accounting Firm Has Expressed Doubt About Our Ability To Continue As A Going Concern, Which May Hinder Our Ability To Obtain Future Financing.

Our consolidated financial statements as of December 31, 2008 were prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm has issued a report that included an explanatory paragraph referring to our recurring losses from operations and net capital deficiency and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Control By Majority Shareholder

Callisto Pharmaceuticals, Inc. currently owns more than 50% of the outstanding Common Stock of the Company. Therefore, Callisto Pharmaceuticals will be able to elect all of the directors of the Company and maintain control of the board of directors and the operations of the Company. It should also be noted that for the most part, authorization to modify the Articles of Incorporation, as amended, requires only majority shareholder consent and approval to modify the amended and restated By- Laws requires authorization of only a majority of the board of directors.

Potential Conflicts Of Interest

Several of our executive officers and directors are also officers and or directors of our principal shareholder, Callisto Pharmaceuticals, Inc and certain of said executive officers and directors are, in turn, the principal shareholders of Callisto Pharmaceuticals. Accordingly, there may be inherent, albeit non-specific, potential conflicts involved in the participation by members of each company's management and audit committees which will oversee questions of possible conflicts of interest and compensation, notwithstanding an effort to appoint independent directors that do not have these inherent conflicts. In addition, the company and its parent do business with each other. In addition, as a matter of practicality, efficiency and appropriate accounting, the cost of certain service (including salaries of executive officers) are allocated, which creates inter-company obligations.

Clinical Trials Involve A Lengthy And Expensive Process With An Uncertain Outcome, And Results Of Earlier Studies And Trials May Not Be Predictive Of Future Trial Results.

In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Table of Contents

Delays In Clinical Testing Could Result In Increased Costs To Us And Delay Our Ability To Generate Revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

We May Be Required To Suspend Or Discontinue Clinical Trials Due To Unexpected Side Effects Or Other Safety Risks That Could Preclude Approval Of Our Product Candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If We Are Unable To Satisfy Regulatory Requirements, We May Not Be Able To Commercialize Our Product Candidates.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States and we will not generate any revenue.

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate as well as the evaluation of our manufacturing process and our contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory review any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.

Table of Contents

The FDA has substantial discretion in the approval process and may either refuse to file our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our product candidates. If the FDA does not file or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval, which might cause us to cease operations.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

If Our Product Candidates Are Unable To Compete Effectively With Marketed Drugs Targeting Similar Indications As Our Product Candidates, Our Commercial Opportunity Will Be Reduced Or Eliminated.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize GI drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to existing GI drugs. If we are unable to compete effectively in the GI drug market and differentiate our products from currently marketed GI drugs, we may never generate meaningful revenue.

Table of Contents

We Currently Have No Sales And Marketing Organization. If We Are Unable To Establish A Direct Sales Force In The United States To Promote Our Products, The Commercial Opportunity For Our Products May Be Diminished.

We currently have no sales and marketing organization. If any of our product candidates are approved by the FDA, we intend to market that product directly to hospitals and other pharmaceutical distribution channels in the United States through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish this sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the United States, we may receive less revenue than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

We May Need Others To Market And Commercialize Our Product Candidates In International Markets.

In the future, if appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. Currently, we do not have any plans to enter international markets. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

If The FDA Does Not Approve Our Contract Manufacturers' Facilities, We May Be Unable To Develop Or Commercialize Our Product Candidates.

We rely on third-party contract manufacturers to manufacture our product candidates, and currently have no plans to develop our own manufacturing facility. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA. If the FDA does not approve these facilities for the manufacture of our product, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for and manufacturing of our product candidates. In addition, our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies for compliance with good manufacturing practices regulations, or cGMPs, and similar foreign standards. These regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified

Table of Contents

personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect the development of our product candidates and our business.

If Product Liability Lawsuits Are Successfully Brought Against Us, We May Incur Substantial Liabilities And May Be Required To Limit Commercialization Of Our Product Candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients;

product recalls;

loss of revenue; and

the inability to commercialize our product candidates.

We have clinical trial liability insurance with a $5,000,000 annual aggregate limit for up to 75 patients participating at the same time in our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Even If We Receive Regulatory Approval For Our Product Candidates, We Will Be Subject To Ongoing Significant Regulatory Obligations And Oversight.

If we receive regulatory approval to sell our product candidates, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to or obtain re-approvals of our contract manufacturers' facilities or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product

recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could

Table of Contents

harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

We Rely On Third Parties To Conduct Our Clinical Trials. If These Third Parties Do Not Successfully Carry Out Their Contractual Duties Or Meet Expected Deadlines, We May Not Be Able To Seek Or Obtain Regulatory Approval For Or Commercialize Our Product Candidates.

We have agreements with third-party contract research organizations, ("CRO" or "CROs"), to provide monitors and to manage data for our clinical programs. We and our CROs are required to comply with current Good Clinical Practices, ("GCP" or "GCPs"), regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. In the future, if we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials for products in clinical development comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If We Fail To Attract And Keep Senior Management And Key Scientific Personnel, We May Be Unable To Successfully Develop Our Product Candidates, Conduct Our Clinical Trials And Commercialize Our Product Candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Gary S. Jacob, Ph.D., our President and Chief Executive Officer and Kunwar Shailubhai, Ph.D., our Chief Scientific Officer. The loss of services of Dr. Jacob or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

We Will Need To Increase The Size Of Our Organization, And We May Experience Difficulties In Managing Growth.

We are a small company with 8 full-time employees as of November 19, 2009. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for

Table of Contents

managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

manage our development efforts effectively;

manage our clinical trials effectively;

integrate additional management, administrative, manufacturing and sales and marketing personnel;

maintain sufficient administrative, accounting and management information systems and controls; and

hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones.

Reimbursement May Not Be Available For Our Product Candidates, Which Would Impede Sales.

Market acceptance and sales of our product candidates may depend on reimbursement policies and health care reform measures. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subject the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

Legislative Or Regulatory Reform Of The Healthcare System May Affect Our Ability To Sell Our Products Profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact upon our ability to

Table of Contents

sell our products profitably. In recent years, new legislation has been proposed in the United States at the federal and state levels that would effect major changes in the healthcare system, either nationally or at the state level.

These proposals have included prescription drug benefit proposals for Medicare beneficiaries introduced in Congress. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has recently been enacted by Congress and signed by the President. Given this legislation's recent enactment, it is still too early to determine its impact on the pharmaceutical industry and our business. Further federal and state proposals are likely. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain additional collaborators and market our products. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by future healthcare reforms.

It Is Difficult And Costly To Protect Our Proprietary Rights, And We May Not Be Able To Ensure Their Protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities.

As of November 19, 2009, we own one issued United States patent and two issued foreign patent. We have six pending United States patent applications and eight pending foreign patent applications. We may file additional patent applications and extensions. Our issued patents and patent applications primarily deal with composition of matter and use related to SP-304; and composition of matter and use of other analogs of the class of GC-C receptor agonists.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are competitive with our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent application;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent application will not result in issued patents;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

13

Table of Contents

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We May Incur Substantial Costs As A Result Of Litigation Or Other Proceedings Relating To Patent And Other Intellectual Property Rights And We May Be Unable To Protect Our Rights To, Or Use, Our Technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or our pending applications or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties

Table of Contents

resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

There Is No Existing Active Trading Market For Our Common Stock.

Our Common Stock is quoted on the OTC Bulletin Board under the symbol "SGYP." There is no active trading market for any of the Company's securities. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for the securities, the ability of holders of the securities to sell their securities, or the prices at which holders may be able to sell their securities.

The Market Price Of The Common Stock May Be Adversely Affected By Several Factors.

The market price of the Common Stock could fluctuate significantly in response to various factors and events, including:

our ability to integrate operations, technology, products and services;

our ability to execute our business plan;

operating results below expectations;

announcements of technological innovations or new products by us or our competitors;

loss of any strategic relationship;

industry developments;

economic and other external factors; and

period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of the Common Stock.

We Have Not Paid Dividends In The Past And Do Not Expect To Pay Dividends In The Future. Any Return On Investment May Be Limited To The Value Of Our Common Stock.

We have never paid cash dividends on our capital stock and do not anticipate paying cash dividends on our capital stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if the Common Stock price appreciates.

If We Fail To Comply With The Rules Under The Sarbanes-Oxley Act Of 2002 Related To Accounting Controls And Procedures, Or, If Material Weaknesses Or Other Deficiencies Are Discovered In Our Internal Accounting Procedures, Our Stock Price Could Decline Significantly And Raising Capital Could Be More Difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if material weaknesses or other deficiencies are discovered in our internal controls, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent auditors addressing these assessments. We have documented and tested our internal control procedures, and we have identified material weaknesses in our internal control over financial reporting and other deficiencies. These material weaknesses and deficiencies could cause investors to lose confidence in our Company and

Table of Contents

result in a decline in our stock price and consequently affect our financial condition. In addition, if we fail to achieve and maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

A Sale Of A Substantial Number Of Shares Of The Common Stock May Cause The Price Of The Common Stock To Decline.

If our stockholders sell substantial amounts of the Common Stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of the Common Stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Table of Contents

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any accompanying prospectus supplement, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as "expects," "anticipates," "intends," "estimates," "plans," "believes," "seeks," "may," "should", "could" or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above, as well as the risk factors referred to on page 3 of this prospectus and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities offered by this prospectus for general corporate purposes, which may include working capital, capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, and the repayment, refinancing, redemption or repurchase of future indebtedness or capital stock. Additional information on the use of net proceeds from the sale of securities offered by this prospectus may be set forth in the prospectus supplement relating to that offering.

THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in

Table of Contents

the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

shares of our common stock;

shares of our preferred stock;

warrants to purchase any of the securities listed above; and/or

units consisting of one or more of the foregoing.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

General

The following description of common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus but is not complete. For the complete terms of our common stock and preferred stock, please refer to our articles of incorporation, as amended, which may be further amended from time to time, any certificates of designation for our preferred stock, and our amended and restated bylaws, as amended from time to time. The Florida Business Corporation Act may also affect the terms of these securities. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any series of these securities in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any common stock or preferred stock we offer under that prospectus supplement may differ from the terms we describe below.

Our authorized capital stock consists of 200,000,000 shares of common stock, $0.0001 par value, and 20,000,000 shares of preferred stock, $0.001 par value. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded. If the approval of our stockholders is not so required, our board of directors may determine not to seek stockholder approval.

Common Stock

As of December 4, 2009, there were 88,423,359 shares of our common stock outstanding. The holders of our common stock are entitled to such dividends as our board of directors may declare from legally available funds. The holders of our common stock are entitled to one vote per share on any matter to be voted upon by stockholders. Our amended and restated articles of incorporation, as amended, and our amended and restated bylaws do not provide for cumulative voting. No holder of our common stock will have any preemptive right to subscribe for any shares of capital stock issued in the future under the Florida Business Corporation Act, our amended and restated articles of incorporation or our amended and restated bylaws. Upon any voluntary or involuntary liquidation, dissolution, or winding up of our affairs, the holders of our common stock are entitled to receive all of our remaining assets legally available for distribution to the stockholders after payment of all our debts and other liabilities, subject to prior distribution rights of our preferred stock, if any.

Table of Contents

Our common stock is quoted on the OTC Bulletin Board under the symbol "SGYP." The transfer agent and registrar for our common stock is StockTrans, Inc.

Preferred Stock

We are currently authorized to issue 20,000,000 shares of preferred stock. As of December 4, 2009, no shares of preferred stock are outstanding.

Our amended and restated articles of incorporation provides that our board of directors may by resolution, without further vote or action by the stockholders, establish one or more classes or series of preferred stock having the number of shares and relative voting rights, designation, dividend rates, liquidation, and other rights, preferences, and limitations as may be fixed by them without further stockholder approval. Once designated by our board of directors, each series of preferred stock will have specific financial and other terms that will be described in a prospectus supplement. The description of the preferred stock that is set forth in any prospectus supplement is not complete without reference to the documents that govern the preferred stock. These include our amended and restated articles of incorporation and any certificates of designation that the board of directors may adopt. Prior to the issuance of shares of each series of preferred stock, the board of directors is required by the Florida Business Corporation Act and the amended and restated articles of incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Florida. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

(a) the number of shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of shares then outstanding) from time to time by action of the board of directors;

(b) the dividend rate and the times of payment of dividends on the shares of that series, whether dividends shall be cumulative, and, if so, from which date;

(c) whether that series shall have voting rights, in addition to the voting rights provided by law, and, if so, the terms of such voting rights;

(d) whether that series shall have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors shall determine;

(e) whether or not the shares of that series shall be redeemable, and, if so, the terms and conditions of such redemption;

(f) whether that series shall have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;

(g) whether or not the shares of the series will have priority over or be on a parity with or be junior to the shares of any other series or class in any respect;

(h) the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of shares of that series; and

(i) any other relative rights, preferences and limitations of that series.

All shares of preferred stock offered hereby will, when issued, be fully paid and nonassessable, including shares of preferred stock issued upon the exercise of preferred stock warrants or subscription rights, if any.

Table of Contents

Although our board of directors has no intention at the present time of doing so, it could authorize the issuance of a series of preferred stock that could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt.

Options

As of December 4, 2009, there were 4,227,988 shares of common stock reserved underlying stock options granted under our equity compensation plans and there were 2,272,012 shares available for future grants under our 2008 Equity Compensation Incentive Plan.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. If there are differences between that prospectus supplement and this prospectus, the prospectus supplement will control. Thus, the statements we make in this section may not apply to a particular series of warrants. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement which includes this prospectus.

General

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we may issue under a separate agreement. We may enter into the warrant agreement with a warrant agent. Each warrant agent may be a bank that we select which has its principal office in the United States and a combined capital and surplus of at least $50,000,000. We may also choose to act as out own warrant agent. We will indicate the name and address of any such warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the warrant agreement under which the warrants will be issued;

Table of Contents

- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- anti-dilution provisions of the warrants, if any;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire or, if the warrants are not continuously exercisable during that period, the specific date or dates on which the warrants will be exercisable;
- the manner in which the warrant agreement and warrants may be modified;
- the identities of the warrant agent and any calculation or other agent for the warrants;
- federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants;
- any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. eastern time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate, and in the applicable prospectus supplement, the information that the holder of the warrant will be required to deliver to the warrant agent.

Until the warrant is properly exercised, no holder of any warrant will be entitled to any rights of a holder of the securities purchasable upon exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Table of Contents

Enforceability of Rights By Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants in accordance with their terms.

Warrant Agreement Will Not Be Qualified Under Trust Indenture Act

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

Governing Law

Each warrant agreement and any warrants issued under the warrant agreements will be governed by New York law.

Calculation Agent

Calculations relating to warrants may be made by a calculation agent, an institution that we appoint as our agent for this purpose. The prospectus supplement for a particular warrant will name the institution that we have appointed to act as the calculation agent for that warrant as of the original issue date for that warrant. We may appoint a different institution to serve as calculation agent from time to time after the original issue date without the consent or notification of the holders.

The calculation agent's determination of any amount of money payable or securities deliverable with respect to a warrant will be final and binding in the absence of manifest error.

DESCRIPTION OF UNITS

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The applicable prospectus supplement will describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any unit agreement under which the units will be issued;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- whether the units will be issued in fully registered or global form.

The applicable prospectus supplement will describe the terms of any units. The preceding description and any description of units in the applicable prospectus supplement does not purport to be

22

Table of Contents

complete and is subject to and is qualified in its entirety by reference to the unit agreement and, if applicable, collateral arrangements and depositary arrangements relating to such units.

PLAN OF DISTRIBUTION

We may sell the securities being offered pursuant to this prospectus through underwriters or dealers, through agents, or directly to one or more purchasers or through a combination of these methods. The applicable prospectus supplement will describe the terms of the offering of the securities, including:

- the name or names of any underwriters, if any, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters' compensation;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to such prevailing market prices; or
- negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment

option will be set forth in the prospectus supplement for those securities.

If we use a dealer in the sale of the securities being offered pursuant to this prospectus or any prospectus supplement, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

Table of Contents

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, any agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the common stock for whom they act as agents in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase common stock directly and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act.

We may provide agents and underwriters with indemnification against particular civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

In addition, we may enter into derivative transactions with third parties (including the writing of options), or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with such a transaction, the third parties may, pursuant to this prospectus and the applicable prospectus supplement, sell securities covered by this prospectus and the applicable prospectus supplement. If so, the third party may use securities borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and the applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

To facilitate an offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In those circumstances, such persons would cover such over-allotments or short positions by purchasing in the open market or by exercising the over-allotment option granted to those persons. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction

Table of Contents

as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Any common stock sold pursuant to a prospectus supplement will be eligible for quotation and trading on the OTC Bulletin Board. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in some states securities 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 complied with

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Sichenzia Ross Friedman Ference LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2008 and 2007 and for the two years in the period ended December 31, 2008 and the period from November 15, 2005 (inception) to December 31, 2008 incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO Seidman, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus constitutes a part of a registration statement on Form S-3 filed under the Securities Act. As permitted by the SEC's rules, this prospectus and any prospectus supplement, which form a part of the registration statement, do not contain all the information that is included in the registration statement. You will find additional information about us in the registration statement. Any statements made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read, without charge, and copy the documents we file at the SEC's public reference rooms in Washington, D.C. at 100 F Street, NE, Room 1580, Washington, DC 20549, or in New York, New York and Chicago, Illinois. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public at no cost from the SEC's website at http://www.sec.gov.

Table of Contents

INCORPORATION OF DOCUMENTS BY REFERENCE

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"):

our Annual Report on Form 10-K for the fiscal year ended December 31, 2008;

our Quarterly Report on Form 10-Q filed on May 20, 2009;

our Quarterly Report on Form 10-Q filed on August 14, 2009;

our Quarterly Report on Form 10-Q filed on November 16, 2009;

our Current Report on Form 8-K filed on July 2, 2009;

our Current Report on Form 8-K filed on October 8, 2009;

our Current Report on Form 8-K filed on November 5, 2009; and

our Current Report on Form 8-K filed on December 7, 2009.

The reports and other documents that we file after the date of this prospectus pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act will update, supplement and supersede the information in this prospectus. You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

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