UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2012

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-35268

SYNERGY PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0505269**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 Lexington Avenue, Suite 1609, New York, New York 10170
(Address of principal executive offices) (Zip Code)

(212) 297-0020
(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Units, each consisting of two shares of Common Stock and one Warrant to purchase one share of Common Stock	The NASDAQ Capital Market
Common Stock, $0.0001 par value	The NASDAQ Global Market
Warrants to purchase Common Stock	The NASDAQ Capital Market

Securities registered pursuant to section 12(g) of the Act:

Title of class: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $164,803,825 on June 30, 2012.

As of March 15, 2013 the registrant had 73,388,287 shares of Common Stock outstanding.

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

FORM 10-K

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PART I

This Report on Form 10-K for Synergy Pharmaceuticals Inc. may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as "may," "will," "expect," "intend," "anticipate," believe," "estimate" and "continue" or similar words. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Factors that may cause such differences include, but are not limited to, those discussed under Item 1A. Risk Factors and elsewhere in this Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission, including the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change.

ITEM 1. BUSINESS.

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 guanylate cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic idiopathic constipation, or CIC, and constipation-predominant irritable bowel syndrome, or IBS-C. CIC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CIC is primarily characterized by constipation symptoms but a majority of these patients report experiencing straining, 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, a second generation GC-C receptor agonist for the treatment of inflammatory bowel diseases, such as ulcerative colitis, or UC.

Our patented GI drug candidates were discovered and developed in-house by our scientists. Today there are few available therapies for CIC and IBS-C, with diarrhea and nausea common side effects of such therapies.

Plecanatide

Plecanatide, our lead investigational drug, is a member of a new class of non-systemic drugs, referred to as guanylate cyclase C (GC-C) agonists. Plecanatide is a synthetic analog of uroguanylin, a natural human hormone that regulates ion and fluid transport in the intestine. Orally-administered, plecanatide binds to the same receptors on the inside of the gastrointestinal tract as uroguanylin, and we believe it is capable of restoring the normal balance of fluid, thus restoring the regular function of the intestine in patients suffering from GI disorders such as CIC and IBS-C.

There are a multitude of causes of constipation including other disease states and certain drug therapies (e.g., narcotics). CIC has no identifiable causes such as these diseases or drugs or physical anomalies. Patients with CIC have had symptoms for 6 months or more and commonly have less than 3 bowel movements a week and often less than one. They suffer from very hard stool and abdominal symptoms such as bloating, discomfort, gas, and a feeling of incomplete evacuation. Over-the counter medications offer only short term relief and are not indicated for chronic treatment. The prescription drugs available have significant side effects and are only effective in less than half of patients treated. Plecanatide offers hope for a more effective and tolerable treatment that can relieve the significant burden CIC places on patients' lives.

We successfully completed a Phase 1 study of plecanatide in healthy volunteers and a Phase IIa clinical trial in patients with CIC. In December 2012, we successfully completed a large multicenter 951-patient, 12 week repeated-oral-dose, placebo-controlled clinical trial of plecanatide in CIC patients. Plecanatide is also being developed to treat IBS-C. We initiated a Phase 2b trial in IBS-C patients in December 2012.

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.

On September 14, 2012, we entered into a binding letter of intent, or LOI, with Ironwood Pharmaceuticals, Inc., or Ironwood, pursuant to which we and Ironwood agreed to enter into a definitive license agreement giving us an exclusive worldwide license to Ironwood's method of use patents on plecanatide for the treatment of CIC and IBS-C. The LOI contemplates a low single digit royalty on net sales of plecanatide and both parties agreed not to challenge each other's patents covering certain GC-C agonists, with the exception that we retain the right to challenge Ironwood's method of use patent on plecanatide.

14-Day Phase 2a Clinical Trial in CIC

Summary. In September, 2010 we completed a Phase 2a randomized, double-blind, placebo-controlled, 14-day repeat, oral, dose-ranging clinical trial of plecanatide in patients with CIC. 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. The trial utilized 78 evaluable patients at 14 sites in the United States. The primary objective of the trial was to evaluate the safety of plecanatide in patients with CIC. 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 who met the modified Rome III criteria of CIC, a standard patient assessment tool used in the diagnosis of patients with CIC. 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 simultaneous bowel movements, or SBMs, and less than three complete 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 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.

12-week Large Multicenter Clinical Trial in CIC

Summary. On January 2, 2013, we announced positive results from our large multicenter clinical trial of plecanatide in patients with CIC. We intend to present full study results at a major scientific meeting in the second quarter of 2013.

Clinical Trial Design .The large multicenter study was a randomized, 12-week, double-blind, placebo-controlled, dose-ranging study. Patients completed a screening visit and a 2-week pre-treatment period to train on study procedures and establish a baseline for each patient. Patients who successfully completed the pre-treatment period were randomized to 0.3, 1.0, or 3.0 mg plecanatide, or placebo for a 12 week treatment period during which time they were required to call in their bowel movement observations and ratings of their associated abdominal symptoms.

During the 12 week treatment period patients were seen every 4 weeks. At the end of the study the patients had a 2 week post treatment period without drug followed by an end of study visit. The primary efficacy end point was a responder analysis based on patients achieving 3 or more complete spontaneous bowel movements (CSBM) per week (with an increase of at least 1 CSBM from baseline) in 9 of the 12 treatment weeks of the study. Safety and tolerability were also assessed.

This large multicenter study was designed to determine whether plecanatide could increase the number of CSBM's and impact other parameters such as stool consistency, straining and time to first bowel movement in patients with CIC. This 12-week study included 951 CIC patients at 113 clinical sites in the United States.

Evidence of increasing efficacy was seen at increasing dose levels. Notably, the 3 mg dose demonstrated a 19% (p=0.009) overall responder rate (compared to placebo of 10.7%), as well as demonstrating a mean increase in CSBMs over the 12-week treatment period of 2.13 (p<0.001). In addition, statistically significant improvements were seen in key secondary endpoints. The incidence of diarrhea at 3 mg was observed to be 9.7% (compared to placebo incidence of 1.3%).

Phase 2b Clinical Trial in Irritable Bowel Syndrome

Irritable bowel syndrome, or IBS, is characterized by symptoms of abdominal pain or discomfort such as cramping, bloating, gas, and constipation or diarrhea or both. IBS-C is the subtype plecanatide is being developed to treat. IBS is one of the most commonly diagnosed Gl illnesses in the United States. As many as 1 in 6 or up to 50 million adult Americans suffer from IBS. About 13 million of them suffer from the IBS-C subtype.

IBS profoundly impacts patients' physical, social and working lives. A quarter of patients describe their abdominal pain as constant. IBS is one of the most common reasons for work or school absenteeism, second only to the common cold. Fewer than 1 in 10 patients say they are satisfied with available IBS treatments. Healthcare systems spend billions of dollars annually to diagnose and treat this disorder. In the U.S. alone, the annual cost of IBS treatment is estimated to be as much as $10 billion in direct medical costs (doctor and hospital visits, diagnostic procedures, etc.)

On December 27, 2012, we commenced a Phase 2b clinical trial of plecanatide to treat patients with IBS-C. This study will be conducted at 70 sites in the U.S. and 350 patients will be enrolled. To qualify for enrollment patients must meet the Rome III criteria for IBS-C as modified for this study. Abdominal pain is a major part of this syndrome and patients need to have pain scores of 3 or more (on a scale of 1 to 10) for 3 days in each of the two pre-treatment weeks. Qualified patients will be randomized to receive 0.3, 1, 3 or 9 mg of plecanatide or placebo once daily for 12 weeks and will be seen at the clinical site once a month during the study. At the end of treatment patients are followed for two weeks and return for an end of study visit. The primary objective of this study is to select doses for the Phase 3 studies based on safety and efficacy endpoints including bowel movements, stool consistency, time to first bowel movement, reduction of abdominal pain, and quality of life measures. We expect this trial will be completed during the first quarter of 2014.

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SP-333

We are developing a second generation GC-C receptor analog, SP-333, for the treatment of inflammatory bowel diseases, or IBD. 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 thought 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.

More than 500,000 Americans are afflicted with UC, a type of IBD that causes chronic inflammation of the colon. Along with Crohn's disease, the other major form of IBD, UC is painful and debilitating, and can lead to other serious and life-threatening complications such as increased incidence of colon cancer. There is currently no medical cure for UC. A considerable medical need exists for the control and treatment of UC. SP-333 has exhibited potent anti-inflammatory activity in animal studies of colitis, displaying a novel mechanism-of-action that we believe might provide a new way to treat UC patients with mild to moderate disease.

On September 7, 2012, we submitted an Investigational New Drug (IND) application for clinical evaluation of SP-333 to treat IBD. On December 28, 2012, we successfully completed a Phase 1 placebo-controlled, dose-escalating, single-dose study of 70 healthy adult volunteers. On January 28, 2013, we commenced a multiple ascending oral dosing study of healthy volunteers in a Phase 1 trial of SP-333.

On February 1, 2011 the U.S. Patent and Trademark Office issued U.S. Patent No. 7,879,802, covering our novel drug candidate SP-333 to treat IBD. The patent entitled “Agonists of Guanylate Cyclase Useful for the Treatment of Gastrointestinal Disorders, Inflammation, Cancer and Other Disorders” specifically claims composition of matter of SP-333 and use in the treatment of human diseases.

FV-100

On August 17, 2012, we entered into an Asset Purchase Agreement with Bristol-Myers Squibb Company and acquired certain assets related to FV-100, an orally available nucleoside analog, for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the agreement provide for an initial base payment of $1 million, subsequent milestone payments covering (i) marketing (FDA) approval and (ii) achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

Manufacturing of our Product Candidates

We do not have any in-house manufacturing capabilities. Our active pharmaceutical ingredients, or APIs, are manufactured for us by third party contractors. Accordingly, unless or until we develop or acquire sufficient manufacturing capabilities, we will depend on third parties to manufacture plecanatide, SP-333, FV-100 and any future APIs that we may develop or acquire. We have executed manufacturing supply agreements for API manufacturing of plecanatide with two suppliers, sufficient to meet our foreseeable clinical trial requirements.

We continue to pursue additional API supply agreements with other manufacturers. We are in the process of selecting at least one more manufacturer to produce our APIs in accordance with current good manufacturing practices, or cGMP, on a commercial scale to meet our future needs. It is a fundamental part of our commercial strategy to maintain two or more API suppliers to ensure continuity in our supply chain.

In addition we believe, based on the ongoing studies to date, that our current formulations of capsules/tablets, or drug products, are both cost effective and meet the stability requirements for pharmaceutical drug products.

Synergy - Callisto Merger

On July 20, 2012, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Callisto Pharmaceuticals, Inc., or Callisto, as amended on October 15, 2012. At the time, Callisto was our largest stockholder and a development stage biopharmaceutical company.

On January 17, 2013, we completed our acquisition of Callisto, pursuant to the Merger Agreement, as amended. As a result of the Merger, each outstanding share of Callisto common stock was converted into the right to receive 0.1799 of one share of our common stock and the 22,295,000 shares of our common stock held by Callisto were canceled. In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by us and converted into a stock option to purchase the number of shares of our common stock that the holder would have received if such holder had exercised such stock option for shares of Callisto common stock prior to the merger and exchanged such shares for shares of our common stock in accordance with the Exchange Ratio. In addition, each Callisto stock option exercisable for shares of our common stock outstanding on January 17, 2013 was assumed by us and each outstanding warrant or obligation to issue a warrant to purchase shares of Callisto common stock, whether or not vested, was cancelled. Upon consummation of the merger the related party balance due from Callisto, $3,305,636 as of December 31, 2012, was eliminated. In connection with the consummation of the merger, we issued a total of

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approximately 28,605,354 shares of our common stock to former Callisto stockholders in exchange for their shares of Callisto common stock.

As Callisto did not have the required inputs, process or outputs, it does not meet the definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of us, effected through exchange of Callisto shares for our shares, and the cancellation of our shares held by Callisto. The excess of our shares issued to Callisto shareholders over our shares held by Callisto is the result of a discount associated with the restricted nature of our shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. On January 17, 2013, the effective date of the merger, we accounted for the merger by assuming Callisto’s net liabilities, of approximately $1.7 million, principally trade payables. Our financial statements will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

Government Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The FDA has very broad enforcement authority and failure to abide by applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approval, refusal to approve pending applications, and criminal prosecution.

FDA Approval Process

We believe that our product candidates will be regulated by the FDA as drugs. No manufacturer may market a new drug until it has submitted an New Drug Application, or NDA, to the FDA, and the FDA has approved it. The steps required before the FDA may approve an NDA generally include:

- preclinical laboratory tests and animal tests conducted in compliance with FDA's good laboratory practice requirements;
- development, manufacture and testing of active pharmaceutical product and dosage forms suitable for human use in compliance with current good manufacturing practices, or GMP;
- the submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its specific intended use(s);
- the submission to the FDA of a New Drug Application, or NDA; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements including good laboratory practices. We must submit the results of the preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the FDA as part of an IND, which must become effective before we may commence human clinical trials. The IND will automatically become effective 30 days after its receipt by the FDA, unless the FDA raises concerns or questions before that time about the conduct of the proposed trials. In such a case, we must work with the FDA to resolve any outstanding concerns before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board for approval. An institutional review board may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the institutional review board's requirements or may impose other conditions.

Clinical trials involve the administration of the product candidate to humans under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are typically conducted in three sequential phases, though the phases may overlap or be combined. In Phase 1, the initial introduction of the drug into healthy human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance and pharmacologic action, as well as to understand how the drug is taken up by and distributed within the body. Phase 2 usually involves studies in a limited patient population (individuals with the disease under study) to:

- evaluate preliminarily the efficacy of the drug for specific, targeted conditions;

- determine dosage tolerance and appropriate dosage as well as other important information about how to design larger Phase 3 trials; and
- identify possible adverse effects and safety risks.

Phase 3 trials generally further evaluate clinical efficacy and test for safety within an expanded patient population. The conduct of the clinical trials is subject to extensive regulation, including compliance with good clinical practice regulations and guidance.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. We may also suspend clinical trials at any time on various grounds.

The results of the preclinical and clinical studies, together with other detailed information, including the manufacture and composition of the product candidate, are submitted to the FDA in the form of an NDA requesting approval to market the drug. FDA approval of the NDA is required before marketing of the product may begin in the U.S. If the NDA contains all pertinent information and data, the FDA will "file" the application and begin review. The FDA may "refuse to file" the NDA if it does not contain all pertinent information and data. In that case, the applicant may resubmit the NDA when it contains the missing information and data. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within 10 months. The review process, however, may be extended by FDA requests for additional information, preclinical or clinical studies, clarification regarding information already provided in the submission, or submission of a risk evaluation and mitigation strategy. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless GMP compliance is satisfactory. FDA also typically inspects facilities responsible for performing animal testing, as well as clinical investigators who participate in clinical trials. The FDA may refuse to approve an NDA if applicable regulatory criteria are not satisfied, or may require additional testing or information. The FDA may also limit the indications for use and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The testing and approval process requires substantial time, effort and financial resources, and our product candidates may not be approved on a timely basis, if at all. The time and expense required to perform the clinical testing necessary to obtain FDA approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. The results of preclinical studies and initial clinical trials of our product candidates are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including difficulty in obtaining enough patients, investigators or product candidate supply. Failure by us to obtain, or any delay in obtaining, regulatory approvals or in complying with requirements could adversely affect the commercialization of product candidates and our ability to receive product or royalty revenues.

Other Regulatory Requirements

After approval, drug products are subject to extensive continuing regulation by the FDA, which include company obligations to manufacture products in accordance with Good Manufacturing Practice, or GMP, maintain and provide to the FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain FDA approval of certain manufacturing or labeling changes, and comply with FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or NDA holder.

We and any manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA’s GMP regulations. GMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet GMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug’s approved labeling (known as “off-label use”), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with

doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from jurisdiction to jurisdiction. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state.

We are also subject to various environmental, health and safety regulations including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials. From time to time, and in the future, our operations may involve the use of hazardous materials.

Competition

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical and biotechnology companies focusing on GI such as Ironwood Pharmaceuticals, Inc., Forest Laboratories, Inc., Takeda

Pharmaceuticals America, Inc., Sucampo Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc. and Shire Plc. Most of our competitors have financial, technical and marketing resources significantly greater than our resources. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain development projects for products to prevent or treat certain diseases targeted by us. The existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect our ability to market the products we develop.

Research and Development Expenses

Research and development costs include expenditures in connection with operating an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, clinical trial insurance. Research and development expenses for the twelve months ended December 31, 2012 were approximately $29 million, as compared to approximately $13 million and $10 million for the twelve months ended December 31, 2011 and 2010, respectively.

In accordance with FASB ASC Topic 730-10-55, Research and Development, we recorded prepaid research and development costs of approximately $926,000 as of December 31, 2012, as compared to approximately $577,000 as of December 31, 2011, for nonrefundable pre-payments for production of drug substance, analytical testing services for our drug candidates, and upcoming clinical trials of plecanatide and SP-333. In accordance with this guidance, we expense deferred research and development costs when drug compound is delivered and services are performed.

Patents and Proprietary Rights

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret or is protected by confidentiality agreements. Accordingly, patents or other proprietary rights are an essential element of our business.

As of December 31, 2012 we had six issued United States patents related to guanylate cyclase agonists. 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 patent that issued on May 9, 2006 has claims directed to the species of plecanatide, whereas the patent that issued on September 21, 2010 has claims directed to a genus of peptides that are identical in length to plecanatide and is inclusive of plecanatide. A third patent covers the composition-of-matter of SP333 issued on February 1, 2011 and expires in 2028. A fourth patent granted October 11, 2011 covers composition-of-matter of analogs related to plecanatide and SP333 and will expire in 2028. A fifth patent granted February 14, 2012 covers a method of treating inflammatory bowel disease using plecanatide and will expire in 2022. A sixth patent granted June 26, 2012 covers additional compositions-of-matter related to plecanatide and SP333 and will expire in 2029.

In addition, we have four granted foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria, 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, Canada and Japan.. We also have a granted foreign patent that covers composition of matter related to SP333 that expires in 2028. This patent covers Switzerland, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, and Netherlands.

Additionally as of December 31, 2012, we had 11 pending United States patent applications and 47 pending foreign patent applications covering plecanatide and SP-333 and various derivatives and analogs. In April 2010, two parties filed an opposition to our granted patent with the European Patent Office. An opposition hearing was held December 14, 2011, which resulted in the European Patent Office issuing the following statement: “Account being taken of the amendments made by the patent proprietor during the opposition proceedings, the patent and the invention to which it relates are found to meet the requirements of the European Patent Convention (Art.101(3)(a)EPC). “In particular, the composition-of-matter claim covering plecanatide was upheld.

As of March 15, 2013 we had three issued United States patents related to FV-100. One of these patents covers the composition-of-matter of FV-100 and was issued on December 11, 2012 and will expire in 2028. The other two cover the precursor and close analogs of FV-100 and were issued on November 8, 2001 and June 3, 2003 and will both expire in 2018. In addition we have 37 granted foreign patents which cover composition-of-matter of FV-100 and expire in 2027. These foreign patents cover Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Pakistan, Poland, Portugal, Romania, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom and the Russian Federation. We also have 44 additional foreign patents that cover the precursor and close analogs of FV-100 and there are also 2 FV-100 foreign patents pending.

On September 14, 2012, we entered into a binding LOI with Ironwood pursuant to which we and Ironwood agreed to enter into a definitive license agreement giving us an exclusive worldwide license to Ironwood’s method of use patents on plecanatide for the treatment of CC and IBS-C. The LOI contemplates a low single digit royalty on net sales of plecanatide and both parties agreed not to challenge each other’s patents covering certain GC-C agonists, with the exception that we retain the right to challenge Ironwood’s method of use patent on plecanatide.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

Employees

As of March 18, 2013, we had 18 full-time employees. We believe our employee relations are satisfactory.

Our Website

Our website address is ***www.synergypharma.com.*** Information found on our website is not incorporated by reference into this report. We make available free of charge through our website our Securities and Exchange Commission, or SEC, filings furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

ITEM 1A.   RISK FACTORS.

RISKS RELATED TO OUR BUSINESS

We are at an early stage of development as a company and 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:

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

All of our existing product candidates are in various stages of development and will require extensive additional preclinical and clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval 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.

We currently do not have any products that are approved for commercial sale. 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 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 December 31, 2012, we had an accumulated deficit of approximately $109.1 million. 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, complete clinical trials, seek regulatory approval and, if we receive FDA approval, commercialize our products. Because of the numerous risks and uncertainties associated with 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.

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, 2012 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 projected future losses along with 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.

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 certain product development programs.

During the twelve months ended December 31, 2012, our operating activities used net cash of approximately $31.1 million. 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;

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- finance our general and administrative expenses;
- prepare regulatory approval applications and seek approvals for plecanatide and other product candidates, including SP-333 and FV-100;
- license or acquire additional technologies;
- manufacture product for clinical trials;
- 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 of manufacturing product;
- 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 impacts 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:

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- 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 or outside 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.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. 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 we believe 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.

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.

Our product candidates may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive preclinical testing and 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. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. 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, timeliness 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 May 2012, the FDA's Center for Drugs Evaluation and Research, or CDER, released 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 guidance. The guidance document represents the FDA's thinking on the clinical evaluation of products for the treatment of IBS. FDA guidance documents, however, do not establish legally 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 guidance document, 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 enforcement actions, including civil and criminal 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, false claims and patients' privacy 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;

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- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and 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 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 defends against it, could cause us to incur significant legal expenses and divert 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-designed and well-controlled pre-clinical testing and 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 is insufficient to support approval of our product candidates for the claimed intended uses. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine 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 adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA 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 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 enrollment 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 two currently approved prescription therapies for the treatment of CC and IBS-C, Amitiza and Linzess. 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, 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 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 that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. 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 our 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.

Currently, we do not have any plans to enter international markets. In the future, if appropriate regulatory approvals are obtained, we may 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. 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 and FV-100, 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 have executed supply agreements with two contract manufacturers sufficient to meet our foreseeable clinical trial requirements. Any curtailment in the availability of plecanatide, however, 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 continue to pursue additional API and drug product supply agreements with other manufacturers. 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 and 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, 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 will not have 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 us 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 bulk APIs, and 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 safety and 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, reimbursement 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 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.

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:

- 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;

- inability to motivate key employees of any acquired businesses; and

- assumption of known and unknown liabilities

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 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 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;

- 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.

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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, GlaxoWellcome withdrew Lotronex (alosetron), which was approved for women with severe diarrhea-prominent IBS, after the manufacturer received numerous reports of adverse events or 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 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 cGCPs, 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 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.

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

We are a small company with 18 employees as of December 31, 2012. 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, 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 coverage and 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 coverage or 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 coverage and reimbursement are not available or are available only at 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 subjects 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 payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or 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 payors 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. 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 Reconciliation Act, or the PPACA. This law will substantially change the way healthcare 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 discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain 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 includes significant changes to the 340B drug discount 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.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not 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 coverage and 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 opportunities. Our results of operations could be materially adversely affected by 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 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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Our clinical activities involve the handling of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our clinical activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, storage, handling and disposal of these hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or if we fail to comply with such laws and regulations, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations or impose sanctions, such as fines, and we could be held liable for any resulting damages or liabilities. We do not currently maintain hazardous materials insurance coverage.

Risks Related to our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure our 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 and 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 December 31, 2012, we have six issued United States patents related to guanylate cyclase agonists. 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 patent that issued on May 9, 2006 has claims directed to the species of plecanatide, whereas the patent that issued on September 21, 2010 has claims directed to a genus of peptides that are identical in length to plecanatide and is inclusive of plecanatide. A third patent covers the composition-of-matter of SP-333 issued on February 1, 2011 and expires in 2028. A fourth patent granted October 11, 2011 covers composition-of-matter of analogs related to plecanatide and SP-333 and will expire in 2028. A fifth patent granted February 14, 2012 covers a method of treating inflammatory bowel disease using plecanatide and will expire in 2022. A sixth patent granted June 26, 2012 covers addition compoosition-of-matter related to plecanatide and SP333 and will expire in 2029. In addition, we have four granted foreign patents which cover composition-of-matter of plecanatide and expire in 2022. These foreign patents cover Austria, 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, Canada, and Japan. We also have a granted foreign patent that covers composition of matter related to SP333 that expires in 2028. This patent covers Switzerland, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, and Netherlands.

Additionally, as of December 31, 2012, we have 11 pending United States patent applications and 47 pending foreign patent applications covering plecanatide and SP-333 and various derivatives and analogs. In April 2010, two parties filed an opposition to our granted patent with the European Patent Office. An opposition hearing was held December 14, 2011, which resulted in the European Patent Office issuing the following statement: Account being taken of the amendments made by the patent proprietor during the opposition proceedings, the patent and the invention to which it relates are found to meet the requirements of the European Patent Convention (Art.101(3)(a)EPC). In particular, the composition-of-matter claim covering plecanatide was upheld.

On September 14, 2012 we entered into a binding letter of intent (the "LOI") with Ironwood Pharmaceuticals, Inc. ("Ironwood") pursuant to which we and Ironwood agreed to enter into a definitive license agreement giving us an exclusive worldwide license to Ironwood's method of use patents on plecanatide for the treatment of chronic constipation. The LOI contemplates a low single digit royalty on net sales of plecanatide and both parties agreed not to challenge each other's patents covering certain GC-C agonists, except that we retain the right to challenge Ironwood's method of use patents on plecanatide.

As of March 15, 2013 we had three issued United States patents related to FV-100. One of these patents covers the composition-of-matter of FV-100 and was issued on December 11, 2012 and will expire in 2028. The other two cover the precursor and close analogs of FV-100 and were issued on November 8, 2001 and June 3, 2003 and will both expire in 2018. In addition we have 37 granted foreign patents which cover composition-of-matter of plecanatide and expire in 2027. These foreign patents cover Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Pakistan, Poland, Portugal, Romania, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom and the Russian Federation. We also have 44 additional foreign patents that cover the precursor and close analogs of FV-100. There are also about 2 foreign patents pending.

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 product candidates but that are not covered by the claims of our patents;
- we may not have been the first to make the inventions covered by our pending patent applications;

- we may 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; and it is possible that our issued patents could be narrowed in scope, invalidated, held to be unenforceable, or circumvented;
- 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 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 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 submissions, 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, documentaries, 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.

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 it 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 our Common Stock

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;
- announcements concerning product development results, including clinical trial results, or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;

- 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 common stock in the foreseeable future. The payment of dividends on our common 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.

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, substantial amounts of our common stock in the public market, including shares issued in connection with the merger with Callisto and 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 our 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.

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;

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- 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.

Our ability to use our net operating loss carry forwards 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 our ability to use our 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, 2012, we had net operating loss carryforwards aggregating approximately $94 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 from July 14, 2008 through July 8, 2010 have resulted in an additional ownership change. As a result of these events, our ability to utilize our operating loss carry forwards is limited.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or, if we discover material weaknesses and 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, or, if we discover 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. If 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 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.

Our certificate of incorporation and bylaws and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our certificate of incorporation and bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 20,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. No preferred stock is currently outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our second amended and restated certificate of incorporation and bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;

- place limitations on the removal of directors; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

We are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits “business combinations” between a publicly-held Delaware corporation and an “interested stockholder,” which is generally defined as a stockholder who becomes a beneficial owner of 15% or more of a Delaware corporation’s voting stock for a three-year period following the date that such stockholder became an interested stockholder.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with our board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None

ITEM 2. PROPERTIES.

Our corporate headquarters located at 420 Lexington Avenue, New York, was subject to a lease which has a monthly rate of approximately $16,000 and expired on March 31, 2012. This facility was provided to us under a space sharing arrangement with Callisto Pharmaceuticals, Inc. On March 30, 2012, we assumed the Callisto lease and extended this lease through March 31, 2014, at a monthly rate of approximately $19,000. On August 28, 2012 we entered into a Lease Modification, Substitution of Space and Extension Agreement with SL Green Graybar Associates. Under the new lease we will be moving our corporate headquarters and clinical development offices to a larger office space the 20th floor of 420 Lexington Avenue. The new lease has a monthly rate of approximately $35,000, expires March 31, 2019.

We also occupy a small laboratory and several offices in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease through December 31, 2013, at a monthly rate of approximately $2,800.

Rent expense for the twelve months ended December 31, 2012 and 2011 totaled approximately $300,000 and $239,000, respectively.

ITEM 3. LEGAL PROCEEDINGS.

On December 22, 2009, we, through our subsidiary, Synergy Advanced Pharmaceuticals, Inc., filed a complaint in the Supreme Court of the State of New York against CapeBio, LLC, CombiMab Inc. and Per Lindell alleging that defendants intentionally breached certain provisions of agreements previously entered into with us. We are requesting that the defendants be permanently restrained and enjoined from breaching such agreements and disgorging all compensation and any and all profits derived from their claimed misappropriation of plaintiff's intellectual property.

On August 9, 2012, a purported stockholder class action complaint was filed in the Supreme Court for the State of New York, captioned Shona Investments v. Callisto Pharmaceuticals, Inc., et al., Civil Action No. 652783/2012. The complaint names as defendants, Callisto, each member of the Board of Callisto (the "***Individual Defendants*** ") and us. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that we aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. We believe the plaintiffs' allegations lack merit and we are contesting them.

On August 31, 2012, a purported stockholder class action complaint was filed in the Court of Chancery of the State of Delaware, captioned Gary Wagner v. Gary S. Jacob, Inc., et al., Case No. 7820-VCP. The complaint names as defendants, Callisto, the Individual Defendants and us. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that we aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. We believe the plaintiffs' allegations lack merit and we are contesting them.

On or about November 2, 2012, counsel for the Delaware plaintiff reached an agreement with counsel for plaintiff in the New York action by which the plaintiffs from the two cases agreed to conduct preliminary injunctive proceedings and discovery related thereto in the New York action only, and during the pendency of which the plaintiff in the Delaware action would effectively stay any prosecution of its case. The parties have discussed the scope of preliminary discovery and document production.

There can be no assurance as to the outcome of these proceedings.

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ITEM 4. Mine Safety Disclosures

Not Applicable.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITES.

Market Prices

From August 11, 2008 until February 18, 2011, our common stock was quoted on the Over the Counter Bulletin Board under the symbol "SGYP.OB." From February 22, 2011 until November 30, 2011 our common stock was traded on the OTC QB under the symbol "SGYP." Since December 1, 2011 our common stock has been traded on The NASDAQ Capital Market under the symbol "SGYP". On February 21, 2013 our common stock began trading on The NASDAQ Global Market under the symbol "SGYP"

The following table shows the reported high and low closing prices per share for our common stock as reported on the Over the Counter Bulletin Board, the OTC QB and The NASDAQ Capital Market during the periods indicated.

	High	Low
Year ended December 31, 2011		
First quarter	$ 10.98(*)	$ 5.72(*)
Second quarter	$ 8.90(*)	$ 6.00(*)
Third quarter	$ 8.70(*)	$ 4.10(*)
Fourth quarter	$ 4.68(*)	$ 3.35(*)
Year ended December 31, 2012		
First quarter	$ 4.48	$ 3.35
Second quarter	$ 5.93	$ 3.90
Third quarter	$ 5.00	$ 3.74
Fourth quarter	$ 5.71	$ 3.03

(*)All per share amounts have been restated to reflect a one for two (1:2) reverse stock split effective November 30, 2011.

Holders of Common Stock

As of March 15, 2013, we had 397 holders of record of our common stock.

Dividends

Historically, we have not declared or paid any cash dividends to the holders of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

Corporate Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the NASDAQ Stock Market (U.S.), the NASDAQ Pharmaceutical Index, and the Russell 3000 Index from August 11, 2008 (the first date that shares of our common stock were publicly traded) through December 31, 2012. The comparison assumes $100 was invested after the market closed on August 11, 2008 in our common stock and in each of the foregoing indices, and it assumes reinvestment of dividends, if any.

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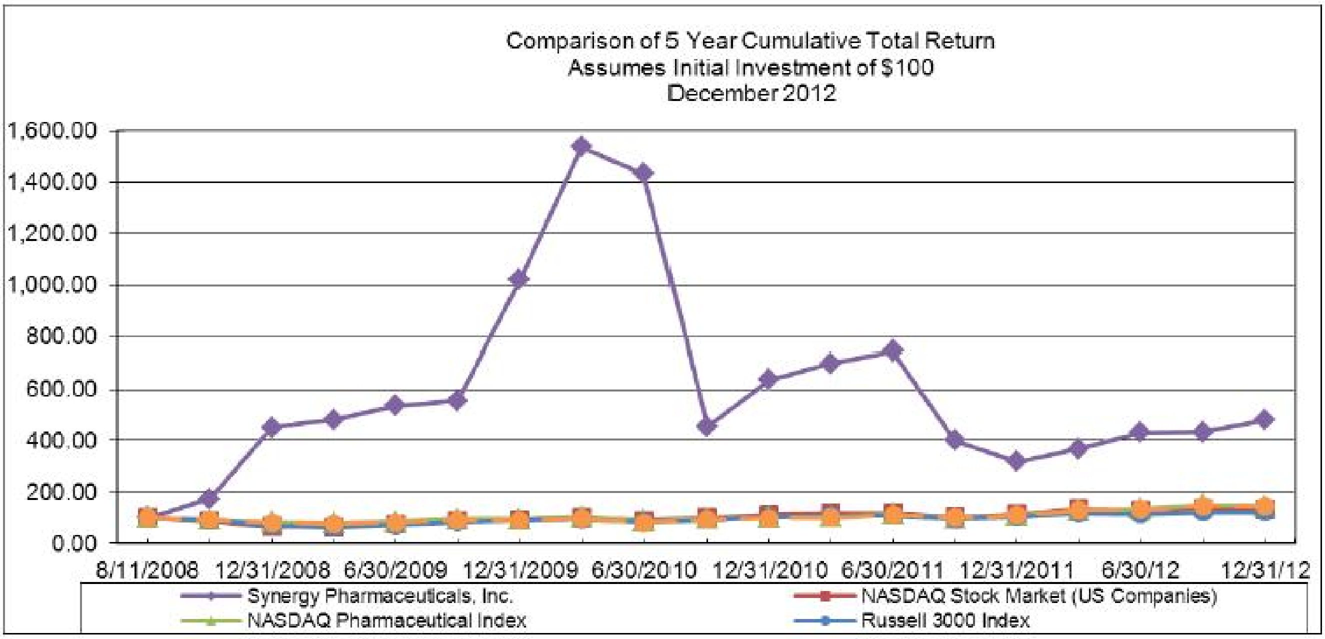
COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN
Among the NASDAQ Stock Market (U.S.),
the NASDAQ Pharmaceutical Index, the Russell 3000 Index
and Synergy Pharmaceuticals, Inc.



Equity Compensation Information

The following table summarizes information about our equity compensation plans as of December 31, 2012.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders	9,734,268	$ 2.75	—
Equity Compensation Plans Not Approved by Stockholders (1)	5,647,203	$ 5.37	—
Total	15,381,471		—

On March 1, 2010, a majority of our shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 7,500,000 shares, giving effect to the one for two (1:2) reverse stock split effective on November 30, 2011.

As of December 31, 2012, there were 9,734,268 stock options outstanding under the 2008 Equity Compensation Incentive Plan, or Plan, and no options outstanding under the 2009 Directors Option Plan, or Directors Plan, with no stock options available for future issuance under the Plan and under the Directors Plan.

On January 17, 2013, our stockholders approved an increase in the number of our common stock shares reserved for issuance under the Plan from 7,500,000 to 15,000,000.

(1) Consists of warrants issued in conjunction with sales of our common stock as well as for consulting and professional services.

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ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth our selected consolidated financial data and has been derived from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2012 and 2011, as well as consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010, and the reports thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with our audited consolidated financial statements and the notes to such statements, included below in Item 8, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included below in Item 7. Historical results are not necessarily indicative of the results to be expected in the future.

	Year ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except for share and per share data)				
Consolidated Statement of Operations Data:					
Revenues	$ —	$ —	$ —	$ —	$ —
Costs and Expenses:					
Research and development	29,294	13,419	9,559	3,733	1,773
Purchased in-process research and development	1,000	—	—	—	28,157
General and administrative	7,941	6,745	6,562	4,467	1,799
Loss from Operations	(38,235)	(20,164)	(16,121)	(8,200)	(31,729)
Other income	506	362	494	—	—
Interest and investment income	218	90	109	75	5
Interest expense	—	(12)	—	—	—
Change in Fair Value of Financial Instruments	(1,933)	5,257	297	—	—
Total Other Income/(Loss)	(1,209)	5,697	900	75	5
Loss from Continuing Operations	(39,444)	(14,467)	(15,221)	(8,125)	(31,724)
Net Loss from Discontinued Operations	—	—	—	—	(32)
Net Loss	$ (39,444)	$ (14,467)	$ (15,221)	$ (8,125)	$ (31,756)
Net Loss per common share, basic and diluted	$ (0.64)	$ (0.30)	$ (0.34)	$ (0.22)	$ (0.54)
Weighted Average Common Shares Outstanding	61,702,277	47,598,240(*)	44,875,356(*)	36,640,664(*)	59,300,248(*)

(*) Weighted average shares outstanding reflects retroactive change of a one for two (1:2) reverse stock split effective on November 30, 2011.

	December 31,				
	2012	2011	2010	2009	2008
	(dollars in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and available-for-sale securities	$ 32,502	$ 13,245	$ 1,708	$ 7,153	$ 216
Working capital	26,734	11,561	(2,307)	6,487	(1,172)
Total assets	37,405	15,870	4,401	9,211	922
Total stockholders' equity	$ 24,832	$ 9,797	$ (4,099)	$ 7,484	$ (1,156)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read this discussion together with the Financial Statements, related Notes and other financial information included elsewhere in this Form 10-K. The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," and elsewhere in this Form 10-K. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements. On November 30, 2011 we filed a certificate of amendment to our amended and restated certificate of incorporation to effect a 1 for 2 reverse split of our common stock. On the effective date, each two shares of our outstanding common stock automatically converted into one share of common stock. All share and per share amounts have been restated for all periods presented to reflect this reverse stock split.

FINANCIAL OPERATIONS 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 idiopathic constipation, or CIC, and constipation-predominant irritable bowel syndrome, or IBS-C. CIC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CIC 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.

On February 14, 2012, we entered into an agreement and plan of merger with our wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation for the purpose of changing our state of incorporation to Delaware from Florida. Pursuant to the merger agreement, we merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation. The directors and officers in office of Synergy Florida upon the effective date of the merger became our directors and officers (Synergy-DE).

From inception through December 31, 2012, we have sustained cumulative net losses of approximately $109,053,000. We currently operate in one reportable business segment—human therapeutics. Substantially all of our resources have been expended for the research and development of our product candidates. From inception through December 31, 2012, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

HISTORY

On July 14, 2008, Pawfect Foods Inc. ("Pawfect"), a Florida corporation incorporated on November 15, 2005, acquired 100% of the common stock of Synergy Pharmaceuticals, Inc. and its wholly-owned subsidiary, Synergy Advanced Pharmaceuticals, Inc. (collectively "Synergy-DE"), a Delaware corporation incorporated on September 11, 1992, under the terms of an Exchange Transaction among Pawfect, Callisto Pharmaceuticals, Inc. ("Callisto'), Synergy-DE, and certain other holders of Synergy-DE common stock ("Exchange Transaction"). For a more detailed discussion of this exchange transaction, see Item 8. Financial Statements—Note 3 *Acquisitions and Stockholders' Equity (Deficit).*

On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its name to Synergy Pharmaceuticals, Inc.

Immediately following the Exchange Transaction we discontinued its pet food business and are now exclusively focused on the development of drugs to treat GI disorders and diseases. We acquired the GI drugs and related technology in connection with the Exchange Transaction.

On May 9, 2012, we closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of $2,952,930. We also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts and commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

On June 21, 2012, we entered into a controlled equity sales agreement with a placement agent and agreed that we may issue and sell through the placement agent, up to $30,000,000 of our common stock. From October 8, 2012 through December 31, 2012, we sold 815,654 shares of common stock with gross proceeds of $4,111,802, at an average selling price of $5.04 per share. Selling agent fees totaled $123,385 on these sales.

On August 23, 2012, we signed an Asset Purchase Agreement with Bristol-Myers Squibb Company and acquired the assets related to FV-100, an orally available nucleoside analogue, currently being developed for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the Agreement provide for an initial payment of $1 million, subsequent milestone payments covering marketing approval and achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

Synergy - Callisto Merger

On July 20, 2012, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Callisto as amended on October 15, 2012. At the time Callisto was our largest stockholder and is a development stage biopharmaceutical company.

On January 17, 2013, we completed our acquisition of Callisto. As a result of the merger, each outstanding share of Callisto common stock was converted into the right to receive 0.1799 of one share of our common stock (the "Exchange Ratio") and the 22,295,000 shares of our common stock held by Callisto were canceled. In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by us and converted into a stock option to purchase the number of shares of our common stock that the holder would have received if such holder had exercised such stock option for shares of Callisto common stock prior to the merger and exchanged such shares for shares of our common stock in accordance with the Exchange Ratio. In addition, each Callisto stock option exercisable for shares of our common stock outstanding on the January 17, 2013 was assumed by us and each outstanding warrant or obligation to issue a warrant to purchase shares of Callisto common stock, whether or not vested, was cancelled. Upon consummation of the merger the related party balance due from Callisto, $3,305,636 as of December 31, 2012, was eliminated. In connection with the consummation of the merger, we issued a total of approximately 28,605,354 shares of our common stock to former Callisto stockholders in exchange for their shares of Callisto common stock.

As Callisto does not have the inputs, process and outputs that meet the definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of us, effected through exchange of Callisto shares for our shares, and the cancellation of our shares held by Callisto. The excess of our shares issued to Callisto shareholders over our shares held by Callisto is the result of a discount associated with the restricted nature of our shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. Upon the effective date of the merger, we will account for the merger by assuming Callisto's net liabilities, of approximately $1.7 million. Our financial statements will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2012 AND DECEMBER 31, 2011

We had no revenues during the twelve months ended December 31, 2012 and 2011 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the twelve months ended December 31, 2012 ("Current Year") increased approximately $15.9 million or 119%, to approximately $29.3 million from $13.4 million for the twelve months ended December 31, 2011 ("Prior Year"). This increase in research and development expenses was largely attributable to a doubling of the development efforts of plecanatide, which accounted for $11.0 million of the increase, and the initiation of clinical development of SP-333 which accounted for $3.3 million of the increase. The following table sets forth our research and development expenses directly related to our product candidates for the twelve months ended December 31, 2012 and 2011. These direct expenses were primarily external costs associated with chemistry, manufacturing, controls including drug substance and product (CMC), as well as preclinical studies and clinical trial costs, as follows:

(dollars in thousands)

	Year Ended December 31,	
Drug candidates	**2012**	**2011**
Plecanatide	$ 22,360	$ 11,870
SP-333	3,298	—
Total direct cost	$ 25,658	$ 11,870
Total indirect cost	3,636	1,549
Total research and development cost	$ 29,294	$ 13,419

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Indirect research and development costs related to in-house staff compensation, facilities, depreciation, share-based compensation and research and development support services are not directly allocated to specific drug candidates were approximately $2 million higher due to (i) higher compensation, employee benefits, and stock based compensation expenses of approximately $2.7 million in the Current Year, as compared to approximately $1.2 million during the Prior Year, as a result of increased staffing levels required to support the our large multicenter trial which was initiated in October 2011 and completed in December 2012,and (ii) higher scientific and regulatory advisory fees and expenses of approximately $0.8 million in the Current Year, as compared to approximately $0.3million during the Prior Year, due to the Investigational New Drug (IND) application for clinical evaluation of SP-333 to treat IBD filed on September 7, 2012, and an IND filing for clinical study of plecanatide in IBS-C patients filed on October 26, 2012.

General and administrative expenses increased $1.2 million or 17%, to approximately $7.9 million for the Current Year from approximately $6.7 million for the Prior Year. These increased expenses were primarily the result of (a) higher legal cost of approximately $1.4 million in the Current Year as compared to approximately $0.5 million during the Prior Year, related to (i) the patent prosecution and defense (Part I, Item 1) , and the class action suit relating to the merger (footnote 6) and (ii) costs associated with defending against merger related class action suits filed in New York and Delaware during the Current Period and (b) higher facilities cost of approximately $1.3 million during Current Year as compared to approximately $0.9 million during the Prior Year.

Net loss for the Current Year was approximately $39.4 million, compared to a net loss of approximately $14.5 million incurred for the Prior Year. This increase in our net loss of approximately $24.9 million or 172% was a result of the increases in operating expenses discussed above plus purchased in-process research and development cost of $1 million on FV-100 (footnote 7), a loss in fair value of derivative instruments-warrants of approximately $1.9 million during the Current Year, as compared to a gain of approximately $5.3 million during the Prior Year. This change in fair value in the Current Year was principally due to an increase in our common stock price from $3.51 as of December 31, 2011 to $5.26 per share on December 31, 2012.

YEARS ENDED DECEMBER 31, 2011 AND DECEMBER 31, 2010

We had no revenues during the twelve months ended December 31, 2011 and 2010 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

For the twelve months ended December 31, 2011, research and development expenses increased $3.8 million or 40% to $13.4 million, compared to $9.6 million during the twelve months ended December 31, 2010. This increase in research and development expenses was primarily attributable to initiating the large multicenter II/III clinical trial of our product candidate plecanatide and the pre-clinical development of SP-333. These clinical and preclinical expenses totaled approximately $10.8 million during the twelve months ended December 31, 2011, as compared to $5.5 million during the twelve months ended December 31, 2010. This increase was offset by lower manufacturing, formulation, testing and packaging of drug product, totaling approximately $1million during the twelve months ended December 31, 2011, as compared to approximately $2.6 million during the twelve months ended December 31, 2010.

For the twelve months ended December 31, 2011, general and administrative expenses increased to approximately $6.7 million, as compared to approximately $6.6 million during the twelve months ended December 31, 2010. This increase was primarily due to higher compensation related expenses, partially offset by lower legal expenses.

Net loss for the twelve months ended December 31, 2011 was approximately $14.5 million as compared to a net loss of approximately $15.2 million incurred for the twelve months ended December 31, 2010. This decrease in our net loss of approximately $0.8 million, or 5% was the result of higher research and development expenses discussed above, more than offset by a gain from the change in fair value of our derivative liability of approximately $5.3 million, as compared to a gain of approximately $0.3 million during the twelve months ended December 31, 2010.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2012, we have approximately $12.4 million of cash and cash equivalents and approximately $20.1 million in available- for- sale- securities. Net cash used in operating activities was approximately $31.1 million for the twelve months ended December 31, 2012 as compared to approximately $21.2 million during the twelve months ended December 31, 2011 and $11.5 million during the twelve months ended December 31. 2010. Net cash provided by financing activities for the twelve months ended December 31, 2012 was approximately $52.1 million as compared to approximately $32.6 million and $6.7 million provided during the twelve months ended December 31, 2011 and 2010, respectively.

As of December 31, 2012 we had working capital of approximately $26.7 million as compared to working capital of approximately $11.6 million on December 31, 2011.

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Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of pharmaceutical research and development programs. We will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities. We cannot be certain that additional 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 business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish 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 consolidated financial statements as of December 31, 2012 have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report on our financial statements that included an explanatory paragraph referring to our projected future losses along with 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 and, ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table is a summary of contractual obligations for the periods indicated that existed as of December 31, 2012, and is based on information appearing in the notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

(dollars in thousands)

	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases	$ 2,752	$ 532	$ 805	$ 1,301	$ 114
Purchase obligations—principally employment and consulting services(1)	6,060	1,971	2,792	1,297	—
Purchase Obligations—Major Vendors(2)	19,380	19,380	—	—	—
Total obligations	$ 28,192	$ 21,883	$ 3,597	$ 2,598	$ 114

(1) Represents salary, bonus, and benefits for remaining term of employment agreements with Gary S. Jacob, CEO, Bernard F Denoyer, Senior Vice President, Finance, Kunwar Shailubhai, Chief Scientific Officer and consulting fees, bonus and benefits for remaining term of consulting agreement with Gabriele M. Cerrone, Chairman.

(2) Represents amounts that will become due upon future delivery of supplies, drug substance and test results from various suppliers, under open purchase orders as of December 31, 2012.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2012.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Item 8. Financial Statements—Note 3 *Summary of Significant Accounting Policies and New Accounting Pronouncements*. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. We believe that the following discussion represents our critical accounting policies.

Financial Instruments - Cash, Cash Equivalents and Marketable Securities

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents. Our marketable securities consist solely of investments in US Treasury Notes and have been classified and accounted for as available-for-sale.

Management determines the appropriate classification of our investments at the time of purchase and reevaluates the available-for-sale designations as of each balance sheet date. Cash equivalents and marketable securities are carried at amounts that approximate fair value due to their short-term maturities. We consider the declines in market value of our marketable securities investment portfolio to be temporary in nature. Fair values were determined for each individual security in the investment portfolio. When evaluating the investments for other-than-temporary impairment, we reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and our intent to sell, or whether it is more likely than not we will be required to sell, the investment before recovery of the investment's amortized cost basis. For the year ended December 31, 2012, we did not consider any of our investments to be other-than-temporarily impaired, and there were no such investments for the year ended December 31, 2011.

Research and Development

Research and development costs include expenditures in connection with operating an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, clinical trial insurance.

We do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all and therefore our research and development costs are expensed as incurred. These include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, and clinical trial insurance. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of biopharmaceutical products to base any estimate of the number of future periods that would be benefited.

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Research and Development* ("ASC Topic 730"). This guidance requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts are recognized as an expense. We adopted ASC Topic 730 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows. As of December 31, 2012 and 2011 we had $926,380 and $577,745, respectively, of such deferred amounts, which are included in prepaid and other current assets on the Company's consolidated balance sheets.

Share-Based Compensation

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options and restricted stock units is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage. Since inception through December 31, 2012 stock-based compensation expense has totaled approximately $5,484,000, or 5.03% of our net loss from inception through December 31, 2012.

ASC Topic 718 *"Compensation—Stock Compensation"* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. We did not issue stock options until the year ended December 31, 2008.

Share-based compensation is recognized as an expense in the financial statements based on the grant date fair value. Upon adoption of ASC Topic 718 *"Compensation—Stock Compensation"* , we selected the Black-Scholes option pricing model as the most appropriate model for determining the estimated fair value for stock-based awards. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. Expected volatility is based on the historical volatility of our stock. Option term is based on the term used by similar public entities. The risk-free interest rate is based on observed interest rate appropriate for the expected term of our employee stock options. Forfeiture rates are estimated based on our historical experience plus management's judgment, at the time of grant.

Fair value of financial instruments

We have adopted FASB ASC 820 *Fair Value Measurements and Disclosures ("ASC 820")* for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. The carrying value of cash and cash equivalents, marketable securities, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments.

ASC 820 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1—Quoted prices for identical instruments in active markets.
- Level 2—Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3—Instruments where significant value drivers are unobservable to third parties.

Warrants

We have issued common stock warrants in connection with the execution of certain equity financings. The fair value of certain warrants, deemed to be derivative instruments, is recorded as a derivative liability under the provisions of FASB ASC 815 *Derivatives and Hedging ("ASC 815")* upon issuance. Subsequently the liability is adjusted to fair value as of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption "Change in fair value of derivative liabilities."

The fair value of warrants deemed to be derivative instruments is determined using the Black-Scholes or Binomial option-pricing models using varying assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus use model-derived valuations where significant value drivers are unobservable to third parties to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820. At December 31, 2012 and 2011 the fair value of such warrants was approximately $5,258,000 and $3,325,000, respectively, which we classified as a long term derivative liability on our balance sheets.

As of December 31, 2012 and 2011 we did not hold any Level 1 or Level 2 marketable securities.

RECENT ACCOUNTING PRONOUNCEMENTS

There are no recent accounting pronouncements affecting us.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

Our cash and cash equivalent primary consists of securities issued by the U.S. government, deposits, and money market deposits managed by commercial banks. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term money marketable funds. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, a sudden change in interest rates would not have a material effect on the fair market value of our portfolio, nor our operating results or cash flows.

Recently, there has been concern in the credit markets regarding the value of a variety of mortgage-backed and auction rate securities and the resulting effect on various securities markets. We do not hold any auction rate securities. We do not believe our cash, and cash equivalents investments have significant risk of default or illiquidity, however, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

Foreign Currency Risk

We have no operations outside the U.S. and do not hold any foreign currency denominated financial instruments.

Effects of Inflation

We do not believe that inflation and changing prices during the years ended December 31, 2012, 2011 and 2010 had a significant impact on our results of operations.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The full text of our audited consolidated financial statements as of December 31, 2012 and 2011 and for the years ended December 31, 2012, 2011 and 2010 and for the period from November 15, 2005 (inception) to December 31, 2012, begins on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

a) Disclosure Controls and Procedures

Our chief executive officer and principle financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the company's management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company.

Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company's principal executive and principal financial officer and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

We conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our principle executive officer and principal financial officer conclude that, at December 31, 2012, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting at December 31, 2012 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded there were no such changes during the quarter ended December 31, 2012.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Synergy Pharmaceuticals Inc.
New York, New York

We have audited Synergy Pharmaceuticals Inc. and Subsidiaries' (a development stage Company) (the "Company") internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting (Item 9A). Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Synergy Pharmaceuticals Inc. and Subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2012 and for the period from November 15, 2005 (inception) to December 31, 2012 and the related consolidated statement of stockholders equity (deficit) for the period from November 15, 2005 (inception) to December 31, 2012 and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/BDO USA, LLP
New York, New York
March 18, 2013

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ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth certain information regarding the directors and executive officers of Synergy Pharmaceuticals Inc. as of March 15, 2013:

Name	Age	Position
Gary S. Jacob	65	President, Chief Executive Officer and Director
Kunwar Shailubhai	55	Chief Scientific Officer
Bernard F. Denoyer	65	Senior Vice President, Finance, Secretary
Gabriele M. Cerrone	40	Chairman, Director
Melvin K. Spigelman	64	Director
John P. Brancaccio	65	Director
Thomas H. Adams	70	Director
Christopher McGuigan	54	Director
Alan F. Joslyn	54	Director

Gary S. Jacob, Ph.D. has served as our President, Chief Executive Officer and a Director since July 2008 and as Chairman of Synergy DE from October 2003 until July 2008. Dr. Jacob served as Chief Executive Officer of Callisto Pharmaceuticals, Inc. from May 2003 until January 2013 and a director from October 2004 until January 2013. Dr. Jacob currently serves as a director of Trovagene, Inc. , a diagnostics company. Dr. Jacob served as Chief Scientific Officer of Synergy DE from 1999 to 2003. Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England. Dr. Jacob's broad management expertise in the pharmaceutical and biotechnology industries provides relevant experience in a number of strategic and operational areas and led to the Board's conclusion that he should serve as a director of our company.

Kunwar Shailubhai, Ph.D., has served as our Chief Scientific Officer since July 2008. From March 2004 until July 2008 he served as Senior Vice President, Drug Discovery, of Synergy DE. From May 2003 until March 2004, Dr. Shailubhai served as Executive Vice President, Research and Development of Synergy DE. From 2001 to April 2003, Dr. Shailubhai held the position of Vice President, Drug Discovery at Synergy DE where he was chiefly responsible for the preclinical development of our GC-C agonist program for drugs to treat colon cancer and GI inflammation. Between 1993 and 2000, he was with Monsanto Company, serving as Group Leader of the cancer chemoprevention group. Dr. Shailubhai previously served as a Senior Staff Fellow at the National Institutes of Health, and as an Assistant Professor at the University of Maryland. Dr. Shailubhai received his Ph.D. in microbiology in 1984 from the University of Baroda, India, and his M.B.A. in 2001 from the University of Missouri, St. Louis.

Bernard F. Denoyer has served as our Senior Vice President, Finance and Secretary since July 2008. From December 2007 until January 2013, Mr. Denoyer served as Senior Vice President, Finance and Secretary of Callisto Pharmaceuticals, Inc. and from January 2004 to November 2007 Mr. Denoyer served as Callisto's Vice President, Finance and Secretary. From October 2000 to December 2003, Mr. Denoyer was an independent consultant providing interim CFO and other services to emerging technology companies, including Callisto and certain portfolio companies of Marsh & McLennan Capital, LLC. From October 1994 until September 2000, Mr. Denoyer served as Chief Financial Officer and Senior Vice President at META Group, Inc., a public information technology research company, where he was instrumental in their 1995 IPO. From 1990 to 1993 he served as Vice President Finance of Environetics, Inc., a pharmaceutical water diagnostic test business, acquired by IDEXX Laboratories, Inc.

Gabriele M. Cerrone has served as our Chairman of the Board of Directors and a consultant since July 2008. From March 1999 to January 2005 Mr. Cerrone served as a Senior Vice President of Investments of Oppenheimer & Co. Inc., a financial services firm. In May 2001, Mr. Cerrone led the restructuring of SIGA Technologies, Inc., a biotechnology company, and served on its board of directors from May 2001 to May 2003. Mr. Cerrone co-founded Trovagene, Inc. (formerly Xenomics, Inc.), a diagnostics company, and served as Co-Chairman from July 2005 until November 2006. Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc., a biotechnology company, and served as Chairman from August 2005 to September 2007, when the company was acquired by Inhibitex, Inc., a biotechnology company. Mr. Cerrone served as a director of Inhibitex, Inc. from September 2007 until February 2012 when it was acquired by Bristol-Myers Squibb Company. Mr. Cerrone currently serves as a director of Trovagene, Inc. Mr. Cerrone is the managing partner of Panetta Partners Ltd., a private investor in both public and private venture capital in the life sciences and technology arena as well as real estate. Mr. Cerrone's experience in finance and investment banking allows him to contribute broad financial and strategic planning expertise and led to the Board's conclusion that he should serve as a director of the company.

Melvin K. Spigelman, M.D. has served as a director of our company since August 2008. Since January 2009, Dr. Spigelman has served as President and CEO and from June 2003 to December 2008 as Director of Research and Development for the Global Alliance for TB Drug Development, a non-profit organization which seeks to accelerate the discovery and development of faster-acting and affordable drugs to fight tuberculosis. Dr. Spigelman was President of Hudson-Douglas Ltd, a consulting company, from June 2001 to June 2003. From 2000 to 2001, Dr. Spigelman served as a Vice President, Global Clinical Centers at Knoll Pharmaceuticals, a pharmaceutical unit of BASF Pharma, and from 1992 to 2000, Dr. Spigelman was the Vice President of Research and Development at Knoll. Dr. Spigelman has been a director of The Medicines Company since September 2005. Dr. Spigelman received a B.A. in engineering from Brown University and an M.D. from The Mount Sinai School of Medicine. Dr. Spigelman's expertise in drug development and management qualifies him to serve as a director of our company.

John P. Brancaccio, a retired CPA, has served as a director of our company since July 2008. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation as well as a director of Trovagene, Inc. . Mr. Brancaccio's chief financial officer experience provides him with valuable financial and accounting expertise which the Board believes qualifies him to serve as a director of our company.

Thomas H. Adams, Ph.D. has served as a director of our company since July 2008. Since June 2005, Dr. Adams has served as a director of IRIS International, Inc., a diagnostics company, and as Chief Technology Officer of IRIS from April 2006 until November 2012 when it was acquired by Danaher Corporation. Dr. Adams served as Chairman and Chief Executive Officer of Leucadia Technologies, a privately held medical-device company, from 1998 to April 2006, when Leucadia was acquired by IRIS. In 1989, Dr. Adams founded Genta, Inc., a publicly held biotechnology company in the field of antisense technology, and served as its Chief Executive Officer until 1997. Dr. Adams founded Gen-Probe, Inc. in 1984 and served as its Chief Executive Officer and Chairman until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Before founding Gen-Probe, Dr. Adams held management positions at Technicon Instruments and the Hyland Division of Baxter Travenol. He has significant public-company experience serving as a director of Biosite Diagnostics, Inc., a publicly held medical research firm, from 1989 to 1998 and as a director of Invitrogen, a publicly held company that develops, manufactures and markets research tools and products, from 2000 to 2002. Dr. Adams currently serves as a director of Xifin, Inc., a private lab billing company and Chairman of the Board of Trovagene, Inc. . Dr. Adams holds a Ph.D. in Biochemistry from the University of California, at Riverside. Dr. Adam's executive leadership, particularly in the healthcare field, and the extensive healthcare expertise he has developed qualifies Dr. Adams to serve as a director of our company.

Christopher McGuigan, M.Sc., Ph.D. has served as a director of our company since July 2008. Since 1995, Dr. McGuigan has been Professor of Medicinal Chemistry, Welsh School of Pharmacy, Cardiff University, UK. He is also Deputy Pro Vice-Chancellor Cardiff University, with responsibility for research. Dr. McGuigan is immediate past president of the International Society for Antiviral Research. Dr. McGuigan has over 200 publications and 20 patents. Dr. McGuigan has Chairman of Departmental Research Committee and Director of Research, Head of Medicinal Chemistry. Dr. McGuigan currently serves as a director of Trovagene, Inc. Dr. McGuigan experience in developing new drug agents from discovery to human clinical trials qualifies him to serve as a director of our company.

Alan F. Joslyn, Ph.D. has served as a director of our company since October 2009. Since August 2011, Dr. Joslyn has been a drug development consultant to Sentinella Pharmaceuticals. From August 2009 to August 2011 Dr. Joslyn served as the Chief Executive Officer of Edusa Pharmaceuticals, a privately held biotechnology company. From 2007 to 2009, Dr. Joslyn served as President and Chief Executive Officer of Mt. Cook Pharma and as Senior Vice President of Research & Development at Penwest Pharmaceuticals from 2004 to 2007. From 1995 to 2004, Dr. Joslyn held a number of leadership positions within Johnson & Johnson focusing on development of gastroenterology products including Propulsid®, Motilium®, Aciphex® and prucalopride. Dr. Joslyn received his B.S. in medicinal chemistry, B.A. in biology and Ph.D. in biochemical pharmacology from the State University of New York at Buffalo. Dr. Joslyn's extensive expertise in gastroenterology and product development qualifies Dr. Joslyn to serve as a director of our company.

Board Leadership Structure and Board's Role in Risk Oversight

Since July 2008, we have separated the roles of Chairman of the Board and Chief Executive Officer. Although the separation of roles has been appropriate for us during that time period, in the view of the board of directors, the advisability of the separation of these roles depends upon the specific circumstances and dynamics of our leadership.

As Chairman of the Board, Mr. Cerrone serves as the primary liaison between the CEO and the independent directors and provides strategic input and counseling to the CEO. With input from other members of the board of directors, committee chairs and management, he presides over meetings of the board of directors. Mr. Cerrone has developed an extensive knowledge of our company, its challenges and opportunities and has a productive working relationship with our senior management team.

The board of directors, as a unified body and through committee participation, organizes the execution of its monitoring and oversight roles and does not expect its Chairman to organize those functions. Our primary rationale for separating the positions of Board Chairman and the CEO is the recognition of the time commitments and activities required to function effectively as Chairman and as the CEO of a company with a relatively flat management structure. The separation of roles has also permitted the board of directors to recruit senior executives into the

CEO position with skills and experience that meet the board of director's planning for the position who may not have extensive public company board experience.

The board of directors has four standing committees—Audit, Compensation, Corporate Governance/Nominating and External Communication Oversight. The membership of each of the board committees is comprised of independent directors, with each of the committees having a separate chairman, each of whom is an independent director. Our non-management members of the board of directors meet in executive session at each board meeting.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of risks the company faces, while the board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The board of directors believes that establishing the right "tone at the top" and that full and open communication between executive management and the board of directors are essential for effective risk management and oversight. Our CEO communicates frequently with members of the board to discuss strategy and challenges facing the company. Senior management usually attends our regular quarterly board meetings and is available to address any questions or concerns raised by the board of directors on risk management-related and any other matters. Each quarter, the board of directors receives presentations from senior management on matters involving our areas of operations.

Director Independence

Our board of directors has determined that a majority of the board consists of members are currently "independent" as that term is defined under current listing standards of NASDAQ.

Compensation of Directors

Upon election to the Board, each non-employee and non-consultant director receives a grant of stock options vesting over three years and having an exercise price equal to the fair market value of the common stock on the date of grant.

Non-employee and non-consultant directors also receive an annual cash fee of $30,000 as well as cash compensation for serving on board committees. Chairpersons of the Audit Committee, Compensation Committee, Corporate Governance/Nominating Committee, and External Communication Oversight Committee receive $15,000, $10,000, $6,500, and $10,000, respectively, and members of such committees receive $7,500, $5,000, $5,000, and $5,000 respectively.

Audit Committee

The Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent registered public accountants, (ii) appointing, replacing and discharging the independent auditors, (iii) pre-approving the professional services provided by the independent auditors, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditors, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditors. The Audit Committee also prepares the Audit Committee report that is required pursuant to the rules of the SEC.

The Audit Committee currently consists of John P. Brancaccio, chairman of the Audit Committee, Christopher McGuigan and Melvin K. Spigelman. Our board of directors has determined that each of Mr. Brancaccio, Dr. McGuigan and Dr. Spigelman is "independent" as that term is defined under applicable SEC and NASDAQ rules. Mr. Brancaccio is our audit committee financial expert. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee which is available on our website at www.synergypharma.com.

Compensation Committee

The Compensation Committee has responsibility for assisting the board of directors in, among other things, evaluating and making recommendations regarding the compensation of the executive officers and directors of our company; assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy; producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC; periodically evaluating the terms and administration of our incentive plans and benefit programs and monitoring of compliance with the legal prohibition on loans to our directors and executive officers.

The Compensation Committee currently consists of Thomas H. Adams, chairman of the Compensation Committee, Melvin K. Spigelman and John P. Brancaccio. Our board of directors has determined that all of the members are "independent" under the current listing standards of NASDAQ. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee which is available on our web site at www.synergypharma.com.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance/Nominating Committee

The Corporate Governance/Nominating Committee has responsibility for assisting the board of directors in, among other things, effecting board organization, membership and function including identifying qualified board nominees; effecting the organization, membership and function of board committees including composition and recommendation of qualified candidates; establishment of and subsequent periodic evaluation of successor planning for the chief executive officer and other executive officers; development and evaluation of criteria for Board membership such as overall qualifications, term limits, age limits and independence; and oversight of compliance with the Corporate Governance Guidelines. The Corporate Governance/Nominating Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors. Potential nominees are identified by the Board of Directors based on the criteria, skills and qualifications that have been recognized by the Corporate Governance/Nominating Committee. While our nomination and corporate governance policy does not prescribe specific diversity standards, the Corporate Governance/Nominating Committee and its independent members seek to identify nominees that have a variety of perspectives, professional experience, education, differences in viewpoints and skills, and personal qualities that will result in a well-rounded Board of Directors.

The Corporate Governance/Nominating Committee currently consists of John Brancaccio, chairman of the Corporate Governance/Nominating Committee, Thomas Adams and Christopher McGuigan. The Board of Directors has determined that all of the members are "independent" under the current listing standards of NASDAQ. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee. A copy of this charter is available at our web site www.synergypharma.com.

External Communication Oversight Committee

The External Communication Oversight Committee has responsibility for (a) establishing, monitoring and reviewing our communication policy, inclusive of communications with shareholders, brokers and analysts, investment banks, and the public, (b) review and advise on new information initiatives, inclusive of formulating key messages, press releases, fact sheets and other digital and print communications related to us, (c) monitor and ensure the accuracy and consistency of all communications platforms related to us, (d) identify and recommend consultancy groups to assist management with promoting us, to relevant groups, (e) assist management in executing the strategies and policies formulated by ECOC, and (f) regularly review and make recommendations to the Board of Directors about composition and charter of the ECOC.

The External Communication Oversight Committee currently consists of Melvin Spigelman, chairman of the External Comminucation Oversight Committee and Alan Joslyn.

Scientific Advisory Board

Andrea Brancale, Ph.D. is Senior Lecturer in Medicinal Chemistry at the Cardiff School of Pharmacy and Pharmaceutical Sciences, Cardiff, Whales, UK. He is an internationally recognized expert in computer-based drug design, with a focus on the use of computer-based techniques to understand biological problems and design novel potential drugs. Dr. Brancale is the Chemistry Editor of Antiviral Chemistry and Chemotherapy and a Committee Chair of the International Society for Antiviral Research, and has more than 100 publications, including original papers in high impact scientific journals and conference proceedings.

Michael Camilleri, M.D., Ph.D. is a Professor of Physiology and Medicine at the Mayo Clinic, Minnesota, MN. He has contributed extensively to the fields of enteric neurosciences, motility, and inflammatory bowel diseases (IBD). Dr. Camilleri is on the editorial boards of a number of prestigious journals including Neurogastroenterology and Motility and American Neurogastroenterology and is President of the American Neurogastroenterology and Motility Society.

Douglas Drossman, M.D. is an Adjunct Professor of Medicine and Psychiatry, UNC School of Medicine, Division of Gastroenterology &Hepatology, and former Co-Director of the UNC Center for Functional GI & Motility Disorders. He is President of the Rome Foundation and Scientific Director and member of the Board of the International Foundation for Functional GI Disorders (IFFGD). He has published extensively in the field of gastroenterology, including the textbook Functional GI Disorders (Rome I, Rome II and Rome III)

Scott Plevy, M.D. is an Associate Professor of Medicine, Microbiology and Immunology at the University of North Carolina School of Medicine, Division of Gastroenterology &Hepatology. He is the Core Director of the Immunotechnology Core in the Center for Gastrointestinal Biology and Disease as well as the Director of the University of North Carolina Federation of Clinical Immunology Societies. Dr. Plevy has contributed significantly to the medical literature on Crohn's disease and ulcerative colitis, and has been the principal investigator on numerous ulcerative colitis and Crohn's disease clinical trials.

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Code of Business Conduct and Ethics

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, executive officers and employees. A copy of that code is available on our corporate website at http://www.synergypharma.com. A copy of our Code of Business Conduct and Ethics will also be provided free of charge upon request to: Secretary, Synergy Pharmaceuticals Inc. 420 Lexington Avenue, Suite 1609, New York, NY 10170.

Compliance With Section 16(A) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during 2012, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Committee Report

Under the rules of the SEC, this Compensation Committee Report is not deemed to be incorporated by reference by any general statement incorporating this Annual Report by reference into any filings with the SEC.

The Compensation Committee has reviewed and discussed the following Compensation Discussion and Analysis with management. Based on this review and these discussions, the Compensation Committee recommended to the Board of Directors that the following Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

Submitted by the Compensation Committee
Thomas Adams, Chairman
John Brancaccio
Melvin K. Spigelman

Compensation Discussion and Analysis

Overview

We compete with many other biotechnology companies in seeking to attract and retain a skilled work force. To meet this challenge, we have developed our compensation structure to enable our management to make decisions regarding our compensation programs, to manage these programs, and to effectively communicate the goals of these programs to our employees and stockholders.

Our compensation philosophy is to offer our employees compensation and benefits that are competitive and that meet our goals of attracting, retaining and motivating highly skilled employees so that we can achieve our financial and strategic objectives.

Utilizing this philosophy, our compensation programs are designed to:

- be "market-based" and reflect the competitive environment for personnel;
- stress our "pay for performance" approach to managing pay levels;
- share risks and rewards with employees at all levels;
- be affordable, within the context of our operating expense model;

- align the interests of our employees with those of our stockholders;
- reflect our values; and
- be fairly and equitably administered.

In addition, as we administer our compensation programs, we plan to:

- evolve and modify our programs to reflect the competitive environment and our changing business needs;

- focus on simplicity, flexibility and choice wherever possible;
- openly communicate the details of our programs with our employees and managers to ensure that our programs and their goals are understood; and
- provide our managers and employees with the tools they need to administer our compensation programs.

Elements of Our Compensation Program

As a total rewards package, we design our compensation program to enable us to attract and retain talented personnel. The individual elements of our compensation program serve to satisfy this larger goal in specific ways as described below.

We design base pay to provide the essential reward for an employee's work, and is required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay are provided to recognize an employee's specific performance achievements. Consistent with our compensation philosophy, we implement a "pay for performance" approach that provides higher levels of compensation to individual employees whose results merit greater rewards. Our managers typically make performance assessments throughout the year, and provide ongoing feedback to employees, provide resources and maximize individual and team performance levels.

We design equity-based compensation, including stock options, to ensure that we have the ability to retain talent over a longer period of time, and to provide optionees with a form of reward that aligns their interests with those of our stockholders.

We also utilize various forms of variable compensation, including cash bonuses that allow us to remain competitive with other companies while providing upside potential to those employees who achieve outstanding results.

Core benefits, such as our basic health benefits, are designed to provide a stable array of support to employees and their families.

The four key elements of our compensation structure are:

- base pay;
- variable pay;
- equity-based pay; and
- benefits.

Consistent with our compensation philosophy, we have structured each element of our rewards package as follows:

Base Pay

We create a set of base pay structures that are both affordable and competitive in relation to the market. We continuously monitor base pay levels within the market and make adjustments to our structures as needed. In general, an employee's base pay level should reflect the employee's overall sustained performance level and contribution to our company over time. We seek to structure the base pay for our top performers to be aggressive in relation to the market.

Our base pay structure originated as an outgrowth of the base pay already in effect for key Callisto Pharmaceuticals' employees who transferred to Synergy Pharmaceuticals at the time it was separated from Callisto Pharmaceuticals in July, 2008. The personnel involved in this process include all of the present top management positions within Synergy—Chairman, Mr. Gabriele Cerrone; CEO, Dr. Gary S. Jacob; Senior Vice President of Finance, Mr. Bernard Denoyer; and Chief Scientific Officer, Dr. Kunwar Shailubhai. Our Compensation Committee also used information made available to us by one of our board members. This information includes an independent Executive Compensation Assessment report prepared in March 2006 by Buck Consultants, an ACS company which provided useful comparative data for analyzing how our base pay compared with other peer companies, recognizing that the comparison of base pay needed to take into account an adjustment for the 2006 data collected for that report. Our comparison was based on a list of sixteen peer public biotechnology companies with market capitalizations ranging from $59.8 million to $403.6 million. These companies consisted of the following comparable biotechnology companies: Acusphere, Inc., Barrier Therapueutics, Inc., Corgentech Inc., Dendreon Corp., Emisphere Technologies, Inc., EpIX Pharmaceuticals, Inc., Favrille, Inc., Genta, Inc., Insmed, Inc., Isis Pharmaceuticals, Inc., Kosan Biosciences, Inc. Neurogen Corporation, Praecis Pharmaceuticals, Inc., Rigel Pharmaceuticals, Inc., Sirna Therapeutics, Inc., and Vion Pharmaceuticals, Inc.

The independent Executive Compensation Assessment report that was used by the Compensation Committee for its analysis of internal compensation was prepared on March 16, 2006. Cash compensation data contained in the report had a common effective date of July 1, 2006. The Compensation Committee computed an adjustment to the data to bring it to “present day” using a 4.1% annual update factor. The “present day” data were then used for the subsequent comparative analyses of executive compensation for our management.

Based on data from the Executive Compensation Assessment report, the Compensation Committee was able to compare the overall compensation for the top management positions described above. This included the following compensation variables: 1) Base Salary or consulting fees, 2) Target Incentive (% of Salary or consulting fee), 3) Target Incentive ($), 4) Total Cash Compensation, 5) Long-term Incentives, and 6) Total Direct Compensation. The Compensation Committee chose to use the aggregate of the compensation variables for each management position that the comparative analysis was performed on. Using the data from the independent Executive Compensation Assessment report that covered the compensation variables, our Compensation Committee was able to compare those data with the overall compensation for our members of top management. This included separate analyses for: Chairman, CEO, Senior VP of Finance and Chief Scientific Officer, respectively. The analyses were guided by the principle that the Compensation Committee would position our compensation levels to be at or below the 50th percentile relative to the compensation levels in the “peer group”. Analyses showed this to be the case for all five members of the management team.

All of our named executive officers were found to have overall compensation levels below those of the peer group.

Variable Pay

We design our variable pay programs to be both affordable and competitive in relation to the market. We monitor the market and adjust our variable pay programs as needed. Our variable pay programs, such as our bonus program, are designed to motivate employees to achieve overall goals. Our programs are designed to avoid entitlements, to align actual payouts with the actual results achieved and to be easy to understand and administer.

Equity-Based Rewards

We design our equity programs to be both affordable and competitive in relation to the market. We monitor the market and applicable accounting, corporate, securities and tax laws and regulations and adjust our equity programs as needed. Stock options and other forms of equity compensation are designed to reflect and reward a high level of sustained individual performance over time. We design our equity programs to align employees’ interests with those of our stockholders.

Benefits Programs

We design our benefits programs to be both affordable and competitive in relation to the market while conforming with local laws and practices. We monitor the market, local laws and practices and adjust our benefits programs as needed. We design our benefits programs to provide an element of core benefits, and to the extent possible, offer options for additional benefits, be tax-effective for employees in each country and balance costs and cost sharing between us and our employees.

Our stock options typically have annual vesting over a three-year period and a term of ten years, in order to encourage a long-term perspective and to encourage key employees to remain with us. We also use performance based vesting in our option grants. Generally, vesting and exercise rights cease upon termination of employment. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents.

Timing of Equity Awards

Only the Compensation Committee may approve stock option grants to our executive officers. Stock options are generally granted at predetermined meetings of the Compensation Committee. On limited occasions, grants may occur upon unanimous written consent of the Compensation Committee, which occurs primarily for the purpose of approving a compensation package for newly hired or promoted executive. The exercise price of a newly granted option is the closing price of our common stock on the date of grant.

Executive Equity Ownership

We encourage our executives to hold a significant equity interest in our company. However, we do not have specific share retention and ownership guidelines for our executives.

Performance-Based Compensation and Financial Restatement

We have not considered or implemented a policy regarding retroactive adjustments to any cash or equity-based incentive compensation paid to our executives and other employees where such payments were predicated upon the achievement of certain financial results that were subsequently the subject of a financial restatement.

Severance and Change in Control Arrangements

Several of our executives have employment and other agreements which provide for severance payment arrangements and/or acceleration of stock option vesting that would be triggered by an acquisition or other change in control of our company. See "—Employment Agreements Control Arrangements" below for a description of the severance and change in control arrangements for our named executive officers.

Effect of Accounting and Tax Treatment on Compensation Decisions

In the review and establishment of our compensation programs, we consider the anticipated accounting and tax implications to us and our executives.

Section 162(m) of the Internal Revenue Code imposes a limit on the amount of compensation that we may deduct in any one year with respect to our chief executive officer and each of our next four most highly compensated executive officers, unless certain specific and detailed criteria are satisfied. Performance-based compensation, as defined in the Internal Revenue Code, is fully deductible if the programs are approved by stockholders and meet other requirements. We believe that grants of equity awards under our existing stock plans qualify as performance-based for purposes of satisfying the conditions of Section 162(m), thereby permitting us to receive a federal income tax deduction in connection with such awards. In general, we have determined that we will not seek to limit executive compensation so that it is deductible under Section 162(m). However, from time to time, we monitor whether it might be in our interests to structure our compensation programs to satisfy the requirements of Section 162(m). We seek to maintain flexibility in compensating our executives in a manner designed to promote our corporate goals and therefore our compensation committee has not adopted a policy requiring all compensation to be deductible. Our compensation committee will continue to assess the impact of Section 162(m) on our compensation practices and determine what further action, if any, is appropriate.

Role of Executives in Executive Compensation Decisions

Our board of directors and our Compensation Committee generally seek input from our Chief Executive Officer, Gary S. Jacob, when discussing the performance of, and compensation levels for executives other than himself. The Compensation Committee also works with Dr. Jacob and our Senior Vice President, Finance evaluating the financial, accounting, tax and retention implications of our various compensation programs. Neither Dr. Jacob nor any of our other executives participates in deliberations relating to his or her compensation.

Chief Executive Officer Compensation for Fiscal Year 2012

On December 28, 2012, Dr. Gary Jacob, Chief Executive Officer and President entered into a new employment agreement with us. This agreement is substantially similar to the previous employment agreement that was entered into on May 2, 2011, except, among other things, the base salary for Dr. Jacob is $425,000 and the term of this agreement begins on January 1, 2013 and ends on December 31, 2016.

Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Dr. Jacob is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our

technology or enter into a joint venture in which we contribute such rights to the joint venture where the enterprise value equals or exceeds a minimum of $250 million during the term of the agreement or the license fees we contract to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or the sum of the license fees actually received in the case of an out license, multiplied by 0.5%. In addition, in the event we engage in a merger transaction or a sale of substantially all of our assets where (i) our enterprise value at the time of the merger or sale equals or exceed $400 million and our stockholders prior to consummation of the merger or sale beneficially own less than 20% of the stock of the surviving entity after consummation of the merger or (ii) our enterprise value at the time of the merger or sale or 12 months after the merger or sale equals or exceed $250 million and our stockholders prior to consummation of the merger or sale beneficially own 20% or more of the stock of the surviving entity after consummation of the merge, Dr. Jacob shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

The Compensation Committee believes that Dr. Jacob's employment agreement incentivizes Dr. Jacob to the maximum extent possible to obtain the highest price possible for shareholders in the event of a sale or merger of our company.

2012 Bonus

On December 10, 2012, the Compensation Committee approved a bonus of $187,500 for each of Dr. Jacob and Mr. Cerrone, each of which was 50% of such individual's base compensation and consulting fee, respectively, for 2012. The Compensation Committee reviewed the following factors in determining the amount of the bonus awarded to each individual.

- Clinical development progress
- Financing of the company

- Recruiting of executives and clinical staff

Dr. Jacob's employment agreement and Mr. Cerrone's consulting agreement allows for an annual bonus equal to 50% of their base compensation and consulting fee, respectively. The Compensation Committee believed that each of Dr. Jacob and Mr. Cerrone did an outstanding job during 2012 in a challenging environment with limited resources.

In making its determination as to whether Dr. Jacob and Mr. Cerrone achieved their performance objectives for awarding 2012 bonus , the Compensation Committee looked at the above-mentioned performance objectives in totality and what the achievement of those performance objectives meant to us and our business. The Compensation Committee did not assign actual levels of achievement to each objective.

2013 Bonus Criteria

As of March 18, 2013, the Compensation Committee had not yet determined the performance criteria for Dr. Jacob's and Mr. Cerrone's 2013 bonus.

Compensation Risk Management

We have considered the risk associated with our compensation policies and practices for all employees, and we believe we have designed our compensation policies and practices in a manner that does not create incentives that could lead to excessive risk taking that would have a material adverse effect on us.

Summary Compensation Table

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Chief Executive Officer, Principal Financial Officer and two other highest paid executive officers whose total annual salary and bonus exceeded $100,000 (collectively, the "named executive officers") for fiscal year 2012.

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Name & Principal Position	Year	Salary	Bonus	Options granted (1)	Total
Gabriele M. Cerrone(2)	2012	$ 375,000	$ 187,500	$ 2,132,897	$ 2,695,397
Chairman	2011	287,139	340,648	1,244,126	1,871,913
	2010	280,250	1,397,762(3)	11,712,727(4)	13,390,739
Gary S. Jacob	2012	375,000	187,500	2,132,897	2,695,397
President, Chief Executive Officer	2011	324,450	346,421	1,244,126	1,914,997
and Director	2010	285,000	189,000	11,712,727(4)	12,186,727
Kunwar Shailubhai	2012	250,000	67,500	217,342	534,842
Chief Scientific Officer	2011	236,907	168,556	622,063	1,027,526
	2010	220,000	—	2,364,795(4)	2,584,795
Bernard Denoyer	2012	200,850	45,170	570,423	816,443
Senior Vice President, Finance and	2011	180,675	54,508	—	235,183
Principal Financial Officer	2010	176,000	—	315,306(4)	491,306

(1) Amounts represent the aggregate grant date fair value in accordance with FASB ASC Topic 718, using the Black-Scholes valuation model.

(2) Mr. Cerrone is a party to a consulting agreement with us and was paid a consulting fee for all periods presented.

(3) $1,211,912 of such amount represents an accrued realization bonus. Mr. Cerrone agreed with us to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit us to defer payment of his bonus we agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws. This bonus was paid in full during the year ended December 31, 2011

(4) Options underlying these amounts vest and are exercisable at $1.40 per share upon a change of control

Grants of Plan-Based Awards

The following table sets forth information regarding stock option awards to our named executive officers under our stock option plans during the fiscal year ended December 31, 2012:

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards ($/Share)	Grant Date Fair Value ($)(1)
Gabriele M. Cerrone	8/7/2012	223,181	$ 3.95	$ 485,067
Gabriele M. Cerrone	12/11/2012	600,000	5.00	1,647,830
Gary S. Jacob	8/7/2012	223,181	3.95	485,067
Gary S. Jacob	12/11/2012	600,000	5.00	1,647,830
Bernard Denoyer	1/26/2012	125,000	3.40	244,409
Bernard Denoyer	8/7/2012	150,000	3.95	326,013
Kunwar Shailubhai	8/7/2012	100,000	3.95	217,342

(1) Amounts represent the aggregate grant date fair value in accordance with FASB ASC Topic 718, using the Black-Scholes valuation model.

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Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options and restricted stock, as well as the exercise prices and expiration dates thereof, as of December 31, 2012.

Name	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Dates	Number of Shares or Units of Restricted Stock That Have Vested (4)
Gabriele M. Cerrone	662,531	2,123,181(1)	$0.50-$5.00	July 3, 2018 - December 11, 2022	187,470
Gary S. Jacob	674,961	2,123,181(1)	$0.50-$5.00	July 3, 2018 - December 11, 2022	187,470
Kunwar Shailubhai	537,526	450,000(2)	$0.50 - $3.95	July 3, 2018 — August 7, 2022	62,441
Bernard F. Denoyer	75,017	295,000(3)	$0.50 - $3.95	July 3, 2018 —August 7, 2022	—

(1) The unexercisable options of 400,000 vest 50% each on December 29, 2013 and 2014 , 900,000 options vest upon change of control, 223,181 options vest one third each on August 7, 2013, 2014, and 2015, and 600,000 options vest one third on December 11, 2013, 2014, and 2015.

(2) The unexercisable options of 200,000 vest 50% each on December 29, 2013and 2014,150,000 options vest upon change of control, and100,000 options vest one third on August 7, 2013, 2014, and 2015.

(3) The unexercisable options of 20,000 vest upon change of control, 125,000 options vest one third on January 26, 2013, 2014, and 2015, and 150,000 options vest on August 7, 2013, 2014, and 2015.

(4) The restricted stock awards vested fully on July 3, 2010.

Director Compensation

The following table sets forth summary information concerning the total compensation earned by our non-employee directors in 2012 for services to our company.

Name	Fees Earned
Melvin K. Spigelman(1)	$ 46,625
John P. Brancaccio(2)	$ 57,125
Thomas H. Adams(3)	$ 46,125
Christopher McGuigan(4)	$ 43,750
Alan Joslyn(5)	$ 34,500

(1) As of December 31, 2012, 212,590 stock options were outstanding, of which 179,336 were exercisable.

(2) As of December 31, 2012, 173,442 stock options were outstanding, of which 138,188 were exercisable.

(3) As of December 31, 2012, 151,996 stock options were outstanding, of which 119,992 were exercisable.

(4) As of December 31, 2012, 154,405 stock options were outstanding, of which 121,901 were exercisable.

(5) As of December 31, 2012, 108,003 stock options were outstanding, of which 60,249 were exercisable.

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Employment Agreements and Change in Control Agreements

Gary S. Jacob, Ph.D.

On December 28, 2012, Dr. Gary Jacob, Chief Executive Officer and President entered into a new employment agreement with us. This agreement is substantially similar to the previous employment agreement that was entered into on May 2, 2011, except, among other things, the base salary for Dr. Jacob is $425,000 and the term of this agreement begins on January 1, 2013 and ends on December 31, 2016.

Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Dr. Jacob is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or enter into a joint venture in which we contribute such rights to the joint venture where the enterprise value equals or exceeds a minimum of $250 million in the term of the agreement or the license fees we contract to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or the sum of the license fees actually received in the case of an out license, multiplied by 0.5%. In addition, in the event we engage in a merger transaction or a sale of substantially all of our assets where (i) our enterprise value at the time of the merger or sale equals or exceed $400 million and our stockholders prior to consummation of the merger or sale beneficially own less than 20% of the stock of the surviving entity after consummation of the merger or (ii) our enterprise value at the time of the merger or sale or 12 months after the merger or sale equals or exceed $250 million and our stockholders prior to consummation of the merger or sale beneficially own 20% or more of the stock of the surviving entity after consummation of the merge, Dr. Jacob shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

If the employment agreement is terminated by us other than for cause or as a result of Dr. Jacob's death or permanent disability or if Dr. Jacob terminates his employment for good reason which includes a change of control, Dr. Jacob shall receive (i) a severance payment equal average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base salary during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination. In the event Dr. Jacob's employment was terminated upon a change of control as of December 31, 2012, he would have been entitled to receive a lump sum payment of $2,598,000, less applicable withholding.

Gabriele M. Cerrone

On December 28, 2012, Gabriele Cerrone, our Chairman, entered into a new consulting agreement with us. This agreement is substantially similar to the previous consulting agreement that was entered on May 2, 2011, except, among other things, the base consulting fee for Mr. Cerrone is $425,000 and the term of this agreement begins on January 1, 2013 and ends on December 31, 2016.

Pursuant to the agreement, Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base consulting fee per year based on meeting certain performance objectives and bonus criteria. Mr. Cerrone is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or enter into a joint venture in which we contribute such rights to the joint venture where the enterprise value equals or exceeds a minimum of $250 million during the term of the agreement or the license fees we contract to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or financing or the sum of the license fees actually received multiplied by 0.5%. In addition, in the event we engage in a merger transaction or a sale of substantially all of our assets where (i) our enterprise value at the time of the merger or sale equals or exceed $400 million and our stockholders prior to consummation of the merger or sale beneficially own less than 20% of the stock of the surviving entity after consummation of the merger or (ii) our enterprise value at the time of the merger or sale or 12 months after the merger or sale equals or exceed $250 million and our stockholders prior to consummation of the merger or sale beneficially own 20% or more of the stock of the surviving entity after consummation of the merge, Mr. Cerrone shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

On October 6, 2010 we achieved the $20 million threshold required for Mr. Cerrone's realization bonus to be accrued on the cumulative gross proceeds of financing transactions since August 1, 2008. This bonus totaled $1,211,912, was deemed compensatory in nature and charged to expense during the year ended December 31, 2010. Mr. Cerrone agreed with us to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit us to defer payment of his bonus we agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws. This bonus was paid in full during the twelve months ended December 31, 2011, which payment does not terminate our indemnification liability.

If the consulting agreement is terminated by us other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to the higher of the aggregate amount of his base consulting fee for the then remaining term of the agreement or twelve times the average monthly base consulting fee paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base consulting fee during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of consulting fee and bonus earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination. In the event Mr. Cerrone's employment was terminated upon a change of control as of December 31, 2012, he would have been entitled to receive a lump sum payment of $2,590,000 less applicable withholding.

Bernard F. Denoyer

On January 20, 2011, Bernard F. Denoyer entered into an executive employment agreement with us in which he agreed to serve as Senior Vice President, Finance. The term of the agreement was effective as of January 20, 2011, continues until January 20, 2012 and is automatically renewed for successive one year periods at the end of each term. Mr. Denoyer's base salary is currently $200,850 as of December 31, 2012 and $215,000 effective January 1, 2013. He is eligible to receive a cash bonus of up to 25% of his base salary per year at the discretion of the Compensation Committee of the Board of Directors. If the employment agreement is terminated by Synergy other than for cause or as a result of Mr. Denoyer's death or permanent disability or if Mr. Denoyer terminates his employment for good reason which includes a change of control, Mr. Denoyer shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iii) payment in respect of compensation earned but not yet paid and (iv) payment of the cost of medical insurance for a period of twelve months following termination. In the event Mr. Denoyer's employment was terminated upon a change of control as of December 31, 2012, he would have been entitled to receive a lump sum payment of $313,146, less applicable withholding

Kunwar Shailubhai

On June 25, 2012, Kunwar Shailubhai entered into an amended and restated employment agreement with us, which amended his previous agreement dated April 6, 2004. In his new agreement, Mr. Shailubhai agreed to serve as Chief Scientific Officer and Executive Vice President. The term of the agreement continues until June 25, 2014 and is automatically renewed for successive one year periods at the end of each term. Mr. Shailubhai's base salary is currently $250,000 as of December 31, 2012 and $270,000 effective January 1, 2013. He is eligible to receive a cash bonus of up to 30% of his base salary per year at the discretion of the Compensation Committee of the Board of Directors. If the employment agreement is terminated by Synergy other than for cause or as a result of Mr. Shailubhai's death or permanent disability or if Mr. Shailubhai terminates his employment for good reason which includes a change of control, Mr. Shailubhai shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iii) payment in respect of compensation earned but not yet paid and (iv) payment of the cost of medical insurance for a period of twelve months following termination. In the event Mr. Shailubhai's employment was terminated upon a change of control as of December 31, 2012, he would have been entitled to receive a lump sum payment of approximately $558,500, less applicable withholdings.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 15, 2013 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) our named executive officers and (iv) all directors and executive officers as a group. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable. Unless otherwise indicated, the address of each beneficial owner listed below is c/o Synergy Pharmaceuticals Inc., 420 Lexington Avenue, Suite 1609, New York, NY 10170.

Name of Beneficial Owner	Number of Shares	Percentage(1)
Executive officers and directors:		
Gabriele M. Cerrone	2,295,493(2)	3.1
Gary S. Jacob, Ph.D.	1,370,186(3)	1.8
Kunwar Shailubhai, Ph.D.	696,800(4)	1.0
Bernard Denoyer	179,581(5)	*
John Brancaccio	189,594(6)	*
Chris McGuigan	121,901(7)	*
Thomas Adams	119,992(8)	*
Melvin K. Spigelman, M.D.	179,336(9)	*

Alan F. Joslyn	60,249(10)	*
All Officers and Directors as a Group (9 persons)	5,213,132(11)	6.8
5% or greater holders:		
R. Merrill Hunter	7,831,057(12)	10.6

*less than 1%

(1) Based on 73,388,287 shares outstanding on March 15, 2013.

(2) Consists of 187,470 shares of common stock held by Mr. Cerrone, 932,033 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone, 880,373 shares of common stock held by Panetta Partners, Ltd and 295,617 shares of common stock issuable upon exercise of warrants held by Panetta Partners, Ltd. Mr. Cerrone is the sole managing partner of Panetta Partners, Ltd. and in such capacity exercises voting and dispositive control over securities owned by Panetta Partners, Ltd. despite him having only a small pecuniary interest in such securities.

(3) Consists of 334,034 shares of common stock, 50,413 shares of common stock issuable upon exercise of warrants and 985,739 shares of common stock issuable upon exercise of stock options.

(4) Consists of 88,017 shares of common stock, 12,788 shares of common stock issuable upon exercise of warrants and 595,995 shares of common stock issuable upon exercise of stock options.

(5) Consists of 2,952 shares of common stock, 1,476 shares of common stock issuable upon exercise of warrants and 175,153 shares of common stock issuable upon exercise of stock options.

(6) Includes 169,150 shares of common stock issuable upon exercise of stock options.

(7) Consists of shares of common stock issuable upon exercise of stock options.

(8) Consists of shares of common stock issuable upon exercise of stock options.

(9) Consists of shares of common stock issuable upon exercise of stock options.

(10) Consists of shares of common stock issuable upon exercise of stock options.

(11) Includes 3,339,548 shares of common stock issuable upon exercise of stock options and 360,294 shares of common stock issuable upon exercise of warrants.

(12) Includes 462,500 shares of common stock issuable upon exercise of warrants.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting and investment power with respect to securities. Beneficial ownership determined in this manner may not constitute ownership of such securities for other purposes or indicate that such person has an economic interest in such securities.

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ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Synergy - Callisto Merger

On July 20, 2012, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Callisto Pharmaceuticals, Inc., or Callisto, as amended on October 15, 2012. At the time, Callisto was our largest stockholder and a development stage biopharmaceutical company.

On January 17, 2013, we completed our acquisition of Callisto, pursuant to the Merger Agreement, as amended,. As a result of the merger, each outstanding share of Callisto common stock was converted into the right to receive 0.1799 of one share of our common stock and the 22,295,000 shares of our common stock held by Callisto were canceled. In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by us and converted into a stock option to purchase the number of shares of our common stock that the holder would have received if such holder had exercised such stock option for shares of Callisto common stock prior to the merger and exchanged such shares for shares of our common stock in accordance with the Exchange Ratio. In addition, each Callisto stock option exercisable for shares of our common stock outstanding on the January 17, 2013 was assumed by us and each outstanding warrant or obligation to issue a warrant to purchase shares of Callisto common stock, whether or not vested, was cancelled.

In connection with the consummation of the merger, we issued a total of approximately 28,605,354 shares of our common stock to former Callisto stockholders in exchange for their shares of Callisto common stock. Each share of our common stock received in connection with the merger is subject to a lock-up beginning on January 17, 2013 and ending on the earlier of (i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the merger agreement), or (iii) our written consent, at our sole discretion, provided our consent shall apply to all shares issued pursuant to the merger.

Upon consummation of the merger, the related party balance due from Callisto, $3,305,636 as of December 31, 2012, was eliminated.

Gabriele M. Cerrone

On December 28, 2012, Gabriele Cerrone, our Chairman, entered into a new consulting agreement with us. This agreement is substantially similar to the previous consulting agreement that was entered on May 2, 2011, except, among other things, the base consulting fee for Mr. Cerrone is $425,000 and the term of this agreement begins on January 1, 2013 and ends on December 31, 2016.

Pursuant to the agreement, Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base consulting fee per year based on meeting certain performance objectives and bonus criteria. Mr. Cerrone is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or enter into a joint venture in which we contribute such rights to the joint venture where the enterprise value equals or exceeds a minimum of $250 million during the term of the agreement or the license fees we contract to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or financing or the sum of the license fees actually received multiplied by 0.5%. In addition, in the event we engage in a merger transaction or a sale of substantially all of our assets where (i) our enterprise value at the time of the merger or sale equals or exceed $400 million and our stockholders prior to consummation of the merger or sale beneficially own less than 20% of the stock of the surviving entity after consummation of the merger or (ii) our enterprise value at the time of the merger or sale or 12 months after the merger or sale equals or exceed $250 million and our stockholders prior to consummation of the merger or sale beneficially own 20% or more of the stock of the surviving entity after consummation of the merge, Mr. Cerrone shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

Conflicts of Interest

Gabriele Cerrone and his affiliates are subject to certain potential conflicts of interests. His consulting agreement expressly recognizes that he may provide consulting services to others. In addition, from time to time, he or his affiliates may be presented with business opportunities which could be suitable for our business and Mr. Cerrone is not subject to any restrictions with respect to other business activities, except to the extent such activities are in violation of our Code of Conduct and Ethics or violate general confidentiality provisions of his consulting agreement. In instances where there is potential conflict of interest or business opportunity, with respect to any officer or director, including Mr. Cerrone, our Audit Committee has both the authority and responsibility to review such matters and take appropriate actions.

Any future transactions with officers, directors or 5% stockholders will be on terms no less favorable to us than could be obtained from independent parties. Any affiliated transactions must be approved by a majority of our independent and disinterested directors who have access to our counsel or independent legal counsel at our expense.

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ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Audit Fees

The aggregate fees billed and unbilled for the fiscal years ended December 31, 2012 and December 31, 2011 for professional services rendered by our principal accountants for the audits of our annual financial statements, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were $335,393 and $307,890, respectively.

Audit-Related Fees

There were no aggregate fees billed for the fiscal year ended December 31, 2012 and 2011 for assurance and related services rendered by our principal accountants related to the performance of the audit or review of our financial statements.

Tax and Other Fees

The aggregate fees billed for the fiscal year ended December 31, 2012 and December 31, 2011 for professional services rendered by our principal accountants for tax compliance were $23,921 and $22,650, respectively.

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

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ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) *List of Documents Filed as a Part of This Report:*

(b) *Index to Financial Statement Schedules:*

All schedules have been omitted because the required information is included in the consolidated financial statements or the notes thereto, or is not applicable or required.

(c) *Index to Exhibits*

The Exhibits listed below are identified by numbers corresponding to the Exhibit Table of Item 601 of Regulation S-K. The Exhibits designated by an asterisk (*) are management contracts or compensatory plans or arrangements required to be filed pursuant to Item 15.

Exhibit No.	Description
1.2	Controlled Equity Offering Sales Agreement dated June 21, 2012 between Synergy Pharmaceuticals Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to Form S-3 filed June 21, 2012).
2.1	Agreement and Plan of Merger dated February 10, 2012 between Synergy Pharmaceuticals, Inc., a Florida corporation and Synergy Pharmaceuticals Inc., a Delaware corporation (incorporated by reference to Exhibit 2.1 to Form 10-K filed March 15, 2012).
2.2	Agreement and Plan of Merger dated as of July 20, 2012 by and among Synergy Pharmaceuticals, Inc. and Callisto Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to Form 8-K filed July 23, 2012).
2.3	Amendment No. 1 to the Agreement and Plan of Merger dated as of October 15, 2012 by and among Synergy Pharmaceuticals Inc. and Callisto Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to Form 8-K filed October 16, 2012).
3.1	Second Amended and Restated Certificate of Incorporation of Synergy Pharmaceuticals Inc. (incorporated by reference to Exhibit 3.1 to Form 10-K filed March 15, 2012).
3.2	Amendment to the Second Amended and Restated Certificate of Incorporation of Synergy Pharmaceuticals Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed January 17, 2013).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Form 10-K filed March 15, 2012).
4.1	2008 Equity Compensation Incentive Plan (incorporated by reference to Exhibit 4.1 to Form 8-K filed July 18, 2008)*
4.2	2009 Directors Stock Option Plan (incorporated by reference to Exhibit 4.2 to Form 10-K filed March 15, 2010)*
4.3	Form of Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.6 to Form S-3 filed November 24, 2009).
4.4	Form of Warrant in connection with June 30, 2010 financing (incorporated by reference to Exhibit 4.1 to Form 8-K filed July 7, 2010).
4.5	Form of Warrant in connection with October 1, 2010 financing (incorporated by reference to Exhibit 4.1 to Form 8-K filed October 5, 2010).

4.6	Form of Warrant in connection with March 4, 2011 financing (incorporated by reference to Exhibit 4.1 to Form 8-K filed March 10, 2011).
4.7	Form of Warrant in connection with October 4, 2011 financing (incorporated by reference to Exhibit 4.1 to Form 8-K filed October 6, 2011).

4.8	Form of Warrant in connection with October 14, 2011 financing (incorporated by reference to Exhibit 4.1 to Form 8-K filed October 14, 2011).
4.9	Form of Warrant in connection with November 17, 2011 financing (incorporated by reference to Exhibit 4.1 to Form 8-K filed November 15, 2011).
4.10	Amended and Restated Synergy Pharmaceuticals, Inc. Warrant Agency Agreement dated as of December 15, 2011 (incorporated by reference to Exhibit 4.1 to Form 8-K filed December 16, 2011).
4.11	Amended and Restated Synergy Pharmaceuticals, Inc. Unit Agency Agreement dated as of December 15, 2011 (incorporated by reference to Exhibit 4.2 to Form 8-K filed December 16, 2011).
10.1	Form of Executive Non-statutory Stock Option Agreement (incorporated by reference to Exhibit 10.4 to Form 8-K filed July 18, 2008)*
10.2	Form of Non-Executive Non-statutory Stock Option Agreement (incorporated by reference to Exhibit 10.5 to Form 8-K filed July 18, 2008)*
10.3	Executive Employment Agreement dated as of December 28, 2012 between Synergy Pharmaceuticals, Inc. and Gary S. Jacob *
10.4	Consulting Agreement dated as of December 28, 2012 between Synergy Pharmaceuticals, Inc. and Gabriele M. Cerrone *
10.5	Master Services Agreement dated July 20, 2010 (incorporated by reference to Exhibit 10.1 to Form 10-Q filed November 9, 2010)**
10.6	Master Services Agreement dated August 5, 2010 (incorporated by reference to Exhibit 10.2 to Form 10-Q filed November 9, 2010)**
10.7	Asset Purchase Agreement dated August 17, 2012 between Synergy Pharmaceuticals Inc. and Bristol-Myers Squibb Company**
10.8	Executive Employment Agreement dated as of January 20, 2011 between Synergy Pharmaceuticals, Inc. and Bernard F. Denoyer (incorporated by reference to Exhibit 10.8 to Form 10-K filed March 15, 2012)*
14	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14 to Form 10-K filed April 15, 2009)
21	List of Subsidiaries (incorporated by reference to Exhibit 21 to Form 10-K filed April 15, 2009)
23	Consent of BDO USA, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Financial statements from the quarterly report on Form 10-Q of Synergy for the quarter ended September 30, 2012, filed on November 13, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statement of Stockholders Equity (Deficit) (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements tagged as blocks of text.

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* Indicates a management contract or compensatory plan or arrangement.

** Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual

Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

SYNERGY PHARMACEUTICALS INC.
(Registrant)

Date: March 18, 2013	By:	/s/ GARY S. JACOB Gary S. Jacob, *President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ GARY S. JACOB Gary S. Jacob	President and Chief Executive Officer (Principal Executive Officer)	March 18, 2013
/s/ BERNARD F. DENOYER Bernard F. Denoyer	Senior Vice President, Finance (Principal Financial and Accounting Officer)	March 18, 2013
/s/ GABRIELE M. CERRONE Gabriele M. Cerrone	Chairman of the Board	March 18, 2013
/s/ MELVIN K. SPIGELMAN Melvin K. Spigelman	Director	March 18, 2013
/s/ ALAN JOSLYN Alan Joslyn	Director	March 18, 2013
/s/ THOMAS H. ADAMS Thomas H. Adams	Director	March 18, 2013
/s/ JOHN BRANCACCIO John Brancaccio	Director	March 18, 2013
/s/ CHRISTOPHER P. MCGUIGAN Christopher P. McGuigan	Director	March 18, 2013

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Synergy Pharmaceuticals, Inc.
New York, New York

We have audited the accompanying consolidated balance sheets of Synergy Pharmaceuticals, Inc. and Subsidiaries (a development stage company) (the "Company") as of December 31, 2012 and 2011, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2012 and for the period from November 15, 2005 (inception) to December 31, 2012 and the related consolidated statements of changes in stockholders' equity (deficit) for the period from November 15, 2005 (inception) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Synergy Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 and for the period from November 15, 2005 (inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
New York, New York
March 18, 2013

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2012	December 31, 2011
Current Assets:		
Cash and cash equivalents	$ 12,416	$ 13,245
Available-for-sale securities	20,086	—
Prepaid expenses and other current assets	1,547	1,063
Total Current Assets	34,049	14,308
Property and equipment, net	30	6
Security deposits	20	14
Due from Callisto Pharmaceuticals, Inc.	3,306	1,542
Total Assets	$ 37,405	$ 15,870
Current Liabilities:		
Accounts payable	$ 5,255	$ 1,416
Accrued expenses	2,060	1,331
Total Current Liabilities	7,315	2,747
Derivative financial instruments, at estimated fair value-warrants	5,258	3,325
Total Liabilities	12,573	6,072
Stockholders' Equity:		

Preferred stock, Authorized 20,000,000 shares at December 31, 2012 and 2011, none outstanding.	—	—
Common stock, par value of $.0001. Authorized 100,000,000 shares at December 31, 2012 and 2011. Issued and outstanding 66,621,832 and 54,279,906 shares at December 31, 2012 and 2011, respectively	7	6
Additional paid-in capital	133,878	79,401
Deficit accumulated during development stage	(109,053)	(69,609)
Total Stockholders' Equity	24,832	9,798
Total Liabilities and Stockholders' Equity	$ 37,405	$ 15,870

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

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,			For the period November 15, 2005 (inception) to
	2012	2011	2010	December 31, 2012
Revenues	$ —	$ —	$ —	$ —
Costs and Expenses:				
Research and development	29,294	13,419	9,559	57,707
Purchased in-process research and development	1,000	—	—	29,157
General and administrative	7,941	6,745	6,562	27,585
Loss from Operations	(38,235)	(20,164)	(16,121)	(114,449)
Other Income /(Loss)				
Interest and investment income	218	90	109	496
Interest expense	—	(12)	—	(12)
Other income	506	362	494	1,363
Change in fair value of derivative instruments—warrants	(1,933)	5,257	297	3,621
Total Other Income/(loss)	(1,209)	5,697	900	5,468
Loss from Continuing Operations	(39,444)	(14,467)	(15,221)	(108,981)
Loss from discontinued operations	—	—	—	(72)
Net loss	$ (39,444)	$ (14,467)	$ (15,221)	$ (109,053)
Weighted Average Common Shares Outstanding				
Basic and Diluted (restated for stock split)	61,702,277	47,598,240	44,875,356	
Net Loss per Common Share, Basic and Diluted				
Net Loss per Common Share, Basic and Diluted	$ (0.64)	$ (0.30)	$ (0.34)	

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

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SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

Deficit

	Common Shares	Common Stock, Par Value	Additional Paid in Capital	Deficit Accumulated during the Development Stage	Total Stockholders' Equity (Deficit)
Balance at inception, November 15, 2005	—	$ —	$ —	$ —	$ —
Sale of unregistered common stock to founder	75,690,608	7	(5)	—	2
Sale of common stock	6,850,000	1	17	—	18
Net loss for the year	—	—	—	—	—
Balance, December 31, 2005	82,540,608	8	12	—	20
Net loss for the year	—	—	—	(20)	(20)
Balance, December 31, 2006	82,540,608	8	12	(20)	—
Capital contribution by shareholders	—	—	9	—	9
Net loss for the year	—	—	—	(20)	(20)
Balance, December 31, 2007	82,540,608	8	21	(40)	(11)
Cancellation of unregistered founder shares	(74,990,604)	(7)	7	—	—
Common stock issued via Exchange Transaction	22,732,380	3	27,277	—	27,280
Common stock issued via private placement—	2,520,833	—	3,025	—	3,025
Fees and expenses related to private placements	—	—	(73)	—	(73)
Stock based compensation expense	—	—	380	—	380
Net loss for the period	—	—	—	(31,757)	(31,757)
Balance, December 31, 2008	32,803,217	4	30,637	(31,797)	(1,156)
Common stock issued via private placements	11,407,213	1	15,969	—	15,970
Fees and expenses related to private placements	—	—	(260)	—	(260)
Common Stocks Issued for services rendered	1,250	—	2	—	2
Stock based compensation expense	—	—	1,052	—	1,052
Net loss for the period	—	—	—	(8,124)	(8,124)
Balance, December 31, 2009	44,211,680	5	47,400	(39,921)	7,484
Common stock issued via registered direct offering and private placement	1,209,000	—	7,179	—	7,179
Fees and expenses related to direct offering	—	—	(468)	—	(468)
Warrants reclassified to derivative liability	—	—	(3,785)	—	(3,785)
Common stock issued to extend lock-up agreements related to unregistered shares	670,933	—	—	—	—
Common stock Issued for services rendered	2,469	—	18	—	18
Stock based compensation expense	—	—	694	—	694
Net loss for the period	—	—	—	(15,221)	(15,221)
Balance, December 31, 2010	46,094,082	5	51,038	(55,142)	(4,099)
Common stock issued via registered direct offerings and private placements	7,733,093	1	34,368	—	34,369
Fees and expenses related to financing transactions — paid in cash	—	—	(2,148)	—	(2,148)
Fees and expenses related to financing transactions — paid in units of common stock and warrants	77,750	—	—	—	—
Warrants classified to derivative liability - net	—	—	(5,094)	—	(5,094)
Common stock issued to make whole certain unregistered shares	215,981	—	—	—	—
Exercise of warrant	80,000	—	415	—	415
Common stock issued for services rendered	79,000	—	341	—	341
Stock based compensation expense	—		481	—	481
Net loss for the period	—	—	—	(14,467)	(14,467)
Balance, December 31, 2011	54,279,906	6	79,401	(69,609)	9,798
Common stock issued via registered direct offering	12,315,654	1	55,861	—	55,862
Fees and expenses related to financing transactions — paid in cash	—	—	(3,774)	—	(3,774)
Common stock issued for services rendered	26,272	—	93	—	93
Stock based compensation expense	—	—	2,297	—	2,297
Net loss for the period	—	—	—	(39,444)	(39,444)
Balance, December 31, 2012	66,621,832	$ 7	$ 133,878	$ (109,053)	$ 24,832

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

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010	Period from November 15, 2005 (Inception) to December 31, 2012
Cash Flows From Operating Activities:				
Net loss	$ (39,444)	$ (14,467)	$ (15,221)	$ (109,053)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	2	2	2	10
Loss on disposal of property and equipment	2	—	—	2
Stock-based compensation expense	2,515	822	712	5,484
Accretion of discount/premium on investment securities	(86)	—	—	(86)
Purchased in-process research and development	—	—	—	28,157
Change in fair value of derivative instruments—warrants	1,933	(5,257)	(297)	(3,621)
Changes in operating assets and liabilities:				
Security deposit	(5)	—	—	(20)
Accounts payable and accrued expenses	4,442	(2,265)	3,286	6,467
Prepaid expenses and other current assets	(484)	(66)	64	(1,547)
Total Adjustments	8,319	(6,764)	3,767	34,846
Net Cash used in Operating Activities	(31,125)	(21,231)	(11,454)	(74,207)
Cash Flows From Investing Activities:				
Net cash paid on Exchange Transaction	—	—	—	(155)
(Loans to) /Repayment from related parties	(1,764)	133	(702)	(3,306)
Purchases of available-for-sale securities	(20,000)			(20,000)
Additions to property and equipment	(28)			(42)
Net Cash (used in) /provided by Investing Activities	(21,792)	133	(702)	(23,503)
Cash Flows From Financing Activities:				
Capital contribution by shareholders	—	—	—	9
Issuance of common stock	—	—	—	2
Proceeds of sale of common stock	55,862	34,369	7,179	116,406
Proceeds from exercise of warrants	—	415	—	415
Proceeds from sale of unregistered common stock to founders	—	—	—	18
Fees and expenses related to sale of common stock	(3,774)	(2,148)	(468)	(6,724)
Net Cash provided by Financing Activities	52,088	32,636	6,711	110,126
Net increase (decrease) in cash and cash equivalents	(829)	11,538	(5,445)	12,416
Cash and cash equivalents at beginning of period	13,245	1,707	7,152	—
Cash and cash equivalents at end of period	$ 12,416	$ 13,245	$ 1,707	$ 12,416
Supplementary disclosure of cash flow information:				
Cash paid for taxes	$ 50	$ 38	$ 31	$ 140
Supplementary disclosure of non-cash investing and financing activities:				
Value of warrants classified to derivative liability-net	$ —	$ 5,094	$ 3,785	$ 8,879
Value of common stock issued to induce stockholders to extend lock-up agreements	$ —	$ —	$ 3,235	$ 3,235

Cash flow activities for the period inception to December 31, 2012 include discontinued operations of Synergy's pet food business prior to July 14, 2008.

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

SYNERGY PHARMACEUTICALS, INC.
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business Overview

Synergy Pharmaceuticals Inc. ("Synergy" or the "Company") is a biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. Its lead product candidate is plecanatide (formerly called SP-304), a guanylyl cyclase C, or GC-C, receptor agonist, to treat GI disorders, primarily chronic idiopathic constipation, or CIC, and constipation-predominant irritable bowel syndrome, or IBS-C. CIC and IBS-C are functional gastrointestinal disorders that afflict millions of sufferers worldwide. CIC 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. Synergy is also developing SP-333, its second generation GC-C receptor agonist for the treatment of gastrointestinal inflammatory diseases, such as ulcerative colitis, or UC.

On August 23, 2012, Synergy signed an Asset Purchase Agreement with Bristol-Myers Squibb Company and acquired the assets related to FV-100, an orally available nucleoside analogue, currently being developed for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the Agreement provide for an initial payment of $1 million, subsequent milestone payments covering marketing approval and achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

On September 14, 2012, Synergy entered into a binding letter of intent (the "LOI") with Ironwood Pharmaceuticals, Inc. ("Ironwood") pursuant to which Synergy and Ironwood agreed to enter into a definitive license agreement giving Synergy an exclusive worldwide license to Ironwood's method of use patents on plecanatide for the treatment of CC and IBS-C. The LOI contemplates a low single digit royalty on net sales of plecanatide and both parties agreed not to challenge each other's patents covering certain GC-C agonists, with the exception that Synergy retains the right to challenge Ironwood's method of use patent on plecanatide.

2. Basis of Presentation and Going Concern

On July 14, 2008, Pawfect Foods Inc. ("Pawfect"), a Florida corporation incorporated on November 15, 2005, acquired 100% of the common stock of Synergy Pharmaceuticals Inc., a Delaware corporation incorporated on September 11, 1992, and its wholly-owned subsidiary, Synergy Advanced Pharmaceuticals, Inc., (collectively "Synergy-DE"), under the terms of an Exchange Agreement among Pawfect, Callisto Pharmaceuticals, Inc. ("Callisto"), Synergy-DE, and certain other holders of Synergy-DE common stock ("Exchange Transaction"). For a more detailed discussion of this Exchange Transaction, see Note 3, *Acquisition and Stockholders' Equity (Deficit)* below.

On July 21, 2008, Pawfect amended its articles of incorporation to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction and changed its name to Synergy Pharmaceuticals, Inc. The acquisition of Synergy-DE was treated as an asset acquisition, since Synergy-DE is a development stage company and does not have the necessary inputs and outputs to meet the definition of a business. The results of operations of Synergy-DE are included in the accompanying consolidated financial statements from the date of acquisition. As a result of the acquisition of Synergy-DE on July 14, 2008, the Company decided to discontinue its pet food business and accordingly, amounts in the consolidated statements of operations and related notes for all historical periods have been restated to reflect these operations as discontinued.

On February 14, 2012, Synergy Pharmaceuticals, Inc., entered into an agreement and plan of merger with its wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation for the purpose of changing the state of incorporation of the Company to Delaware from Florida. Pursuant to the merger agreement, Synergy merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation. The directors and officers in office of Synergy upon the effective date of the merger became the directors and officers of Synergy-DE.

These consolidated financial statements include Synergy Pharmaceuticals Inc., a Delaware corporation, and subsidiaries: (1) Synergy Advanced Pharmaceuticals, Inc. and (2) IgX, Ltd (Ireland—inactive) (henceforth "Synergy"). All intercompany balances and transactions have been eliminated. These consolidated financial statements as of December 31, 2012 have been prepared under the assumption that we will continue as a going concern. Synergy's independent registered public accounting firm has issued a report on our financial statements that included an explanatory paragraph referring to our projected future losses along with recurring losses from operations and expressing substantial doubt in Synergy's ability to continue as a going concern without additional capital becoming available. Synergy's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On November 29, 2011 Synergy filed an amendment to its amended and restated articles of incorporation pursuant to which Synergy affected a one for two (1:2) reverse stock split on its authorized and issued and outstanding shares of Common Stock effective on

November 30, 2011. All share and per share information has been adjusted to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented, (e.g. inception November 15, 2005).

As of December 31, 2012, Synergy had an accumulated deficit of approximately $109,053,000 and expects to incur significant and increasing operating losses for the next several years as the Company continues to expand its research and development and clinical trials of plecanatide for the treatment of GI diseases and disorders, acquires or licenses technologies, advances other product candidates into clinical development, seeks regulatory approval and, if FDA approval is received, commercializes products. Because of the numerous risks and uncertainties associated with product development efforts, Synergy is unable to predict the extent of any future losses or when Synergy will become profitable, if at all.

Net cash used in operating activities was approximately $31,125,000 for the twelve months ended December 31, 2012. As of December 31, 2012, Synergy had approximately $12,416,000 of cash and cash equivalents and $20,086,000 in available for sale securities. During the twelve months ended December 31, 2012, Synergy incurred net losses from operations of approximately $38,235,000. To date, Synergy's sources of cash have been primarily limited to the sale of common stock. Net cash provided by financing activities for the twelve months ended December 31, 2012 was approximately $52,088,000. As of December 31, 2012 Synergy had a working capital of approximately $26,734,000.

Synergy will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Synergy cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Synergy raises additional funds by issuing equity securities, Synergy's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Synergy's ability to conduct business. If Synergy is unable to raise additional capital when required or on acceptable terms, Synergy may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that Synergy would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

Cash, Cash Equivalents and Marketable Securities

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents. As of December 31, 2012, the amount of cash and cash equivalents was approximately $12 million and consists of checking accounts, short-term money market funds held at U.S. commercial banks. As of December 31, 2011, the amount of cash and cash equivalent was approximately $13 million and consists of checking accounts and short-term money market funds with U.S. commercial banks. At any point in time, the Company's balance of cash and cash equivalent may exceed federally insured limits.

The Company's marketable securities as of December 31, 2012 consist of $20 million in U.S. Treasury securities and have been classified and accounted for as available-for-sale. Management determines the appropriate classification of its investments at the time of purchase and reevaluates the available-for-sale designations as of each balance sheet date. Cash equivalents and marketable securities are carried at amounts that approximate fair value due to their short-term maturities. As of December 31, 2012, gross unrealized losses were not material. The Company recognized no net realized gains or losses for the year ended December 31, 2012. The Company considers the declines in market value of its marketable securities investment portfolio to be temporary in nature. Fair values were determined for each individual security in the investment portfolio. When evaluating the investments for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's amortized cost basis. During the year ended December 31, 2012, the Company did not recognize any impairment charges. As of December 31, 2012, the Company did not consider any of its investments to be other-than-temporarily impaired. There was no investment in marketable securities for the year ended December 31, 2011.

Derivative Instruments

The Company's derivative liabilities are related to warrants issued in connection with financing transactions and are therefore not designated as hedging instruments. All derivatives are recorded on the Company's balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments. Changes in fair value are recorded in the Company's statement of operations.

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Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") Subtopic 820-10, the Company measures certain assets and liabilities at fair value on a recurring basis using the three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers include:

- Level 1, defined as observable inputs such as quoted prices for identical assets in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring management to develop its own assumptions based on best estimates of what market participants would use in pricing an asset or liability at the reporting date.

Financial instruments consist of cash and cash equivalents, marketable securities, accounts payable and derivative instruments. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short term nature, except derivative instruments which are marked to market at the end of each reporting period.

Property, equipment and depreciation

Expenditures for additions, renewals and improvements are capitalized at cost. Depreciation is generally computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the major classes of depreciable assets are 2 to 5 years for equipment and furniture and fixtures. Leasehold improvements are depreciated over the remaining useful life of the lease. Expenditures for repairs and maintenance are charged to operations as incurred. Synergy periodically evaluates whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable.

Income Taxes

Income taxes have been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial statement and tax bases of Synergy's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment.

Contingencies

In the normal course of business, Synergy is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with FASB ASC Topic 450, *Accounting for Contingencies*, ("ASC Topic 450"), Synergy records accruals for such loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Synergy, in accordance with this guidance, does not recognize gain contingencies until realized. For a discussion of contingencies, see Note 6, *Commitments and Contingencies* below.

Research and Development

Research and development costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring, and clinical trial insurance.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of $926,380 as of December 31, 2012, as compared to $577,745 as of December 31, 2011, for nonrefundable pre-payments for production of drug substance, analytical testing services for its drug candidates, and clinical trials. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share* , ("ASC Topic 260") for all periods presented. In accordance with this guide, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Diluted weighted-average shares are the same as

basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. For the years ended December 31, 2012, 2011 and 2010 the effect of 9,734,268, 5,964,039, and 4,302,008, respectively, outstanding stock options and 5,647,203, 5,597,203, and 728,469 respectively, outstanding warrants were excluded from the calculation of diluted loss per share because the effect was antidilutive.

Recent Accounting Pronouncements

There are no recent accounting pronouncements affecting the Company.

3. Acquisition and Stockholders' Equity (Deficit)

On July 14, 2008, Pawfect acquired 100% of the common stock of Synergy-DE from Callisto and certain other holders of Synergy-DE shares, in exchange for 22,732,380 unregistered shares of Pawfect's common stock. This represented approximately 70% of Pawfect's outstanding common stock after giving effect to (i) a 37.845338 for one stock split, (ii) cancellation of 74,990,604 of 75,690,603 unregistered shares owned by Pawfect's principal stockholder and (iii) a $3,000,000 private placement of 2,500,000 unregistered shares of Pawfect's common stock to private investors. Fees and expenses directly related to the closing of this private placement totaled $73,088, yielding net proceeds of $2,926,912. The stock split and change in par value, from $0.001 to $0.0001, resulted in the restatement of all historical common stock and additional paid-in capital amounts presented in the accompanying financial statements.

These transactions were completed under the terms of an Exchange Agreement dated as of July 11, 2008, as amended and effective on July 14, 2008 among Pawfect, Callisto, Synergy-DE, and certain other holders of Synergy-DE common stock. Callisto received 22,295,000 of the 22,732,380 shares of Pawfect's common stock exchanged for ownership of Synergy-DE, and Callisto which represented 68% of Pawfect's outstanding common stock. See Note 4, *Accounting for Share-Based Payments* below for shares issued to other holders.

The Exchange Transaction was treated as an asset acquisition by Pawfect for accounting purposes. Under this method of accounting, Pawfect is treated as the acquiring entity, issuing stock for the assets and liabilities of Synergy-DE. The assets and liabilities of Synergy-DE, primarily cash and accounts payable, were stated at their fair value. Net liabilities acquired totaled $877,646. The fair value of the 22,727,380 shares issued in connection with the Exchange Transaction, totaled $27,278,856 on July 14, 2008, based on a per share value of $1.20, which was the per share price the Company's 2,500,000 common shares sold for in a private placement on that date. The total consideration of $28,156,502 was allocated in full to the Synergy research and development projects which had not yet reached technological feasibility and, having no alternative use, this amount was charged to purchased in-process research and development ("IPR&D") expense as of the date of the Exchange Transaction.

In addition to purchased IPR&D, the Company retained four full time employees and acquired a patent related to the technologies acquired. There were no other intangible assets acquired which required allocation of the purchase price. The Company did not assign a value to the acquired employees as all continuing research and development is being performed under the supervision of other Company employees, nor the patent since the technology is still in an early stage. Therefore, the full purchase price accordingly allocated to purchased in-process research and development and there was no value assigned to goodwill. The value of the IPR&D was based on the fair value of the consideration given which was the value most reliably measurable. Net liabilities assumed in excess of Synergy-DE assets acquired in connection with the Exchange Transaction on July 14, 2008 were as follows:

Assets	
Cash	$ 194,674
Total assets acquired	194,674
Liabilities	
Accounts payable and other liabilities	(722,320)
Due to Callisto	(350,000)
Total liabilities assumed	(1,072,320)
Net liabilities assumed in excess of assets acquired	(877,646)
Fair value of shares issued to Synergy-DE shareholders	(27,278,856)
Total consideration paid by Pawfect to acquire Synergy-DE	$ (28,156,502)

On July 14, 2008, Synergy discontinued its pet food business and exclusively focused on continuing the development of drugs to treat GI disorders and diseases acquired in connection with the Exchange Transaction.

On July 21, 2008, Pawfect amended its articles of incorporation in the State of Florida to effect the actions necessary to complete the transactions contemplated by the Exchange Transaction, including: (i) an increase in the authorized number of common shares from 25,000,000 to 75,000,000 (ii) authorized 20,000,000 shares of preferred stock (iii) changed the common stock par value per share from $0.001 to $0.0001and (iv) changed its name to Synergy Pharmaceuticals, Inc.

During the twelve months ended December 31, 2009 Synergy sold 11,407,213 shares of unregistered common stock at $1.40 per share to private investors, pursuant to a Securities Purchase Agreement, for aggregate proceeds of $15,970,100. There were no warrants issued in connection with these transactions. Synergy incurred $260,002 in fees to selling agents and attorneys in connection with these transactions. Pursuant to the Securities Purchase Agreement the investors agreed to be subject to a lock-up until August 15, 2010 and Synergy agreed to price protection for the investors in the event of subsequent sales of equity securities as defined, until February 15, 2011. In accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the price protection provisions are embedded derivatives that require bifurcation and recognition at fair value in the Company's financial statements. The Company has determined that the fair value of the derivatives is de minimus.

On November 20, 2009, the number of common shares authorized increased from 75,000,000 to 100,000,000.

On June 30, 2010, Synergy entered into securities purchase agreements to sell securities to non-U.S. investors and raised gross proceeds of approximately $2,754,000 in a registered direct offering. Synergy sold 324,000 units at $8.50 per share to investors. Each unit consists of one share of Synergy's common stock and one warrant to purchase one additional share of Synergy's common stock. The warrants expire after five years and are exercisable at $9.00 per share. The offering was made pursuant to a shelf registration statement on Form S-3 (the base prospectus effective December 10, 2009), as supplemented by a prospectus supplement filed with the Securities and Exchange Commission on June 23, 2010. As of June 30, 2010, Synergy had received proceeds of $255,000, less legal fees of $25,000 associated with this offering. The remaining $2,499,000 was held in escrow and received by Synergy on July 2 and July 8, 2010. In July 2010, the Company paid an aggregate $261,630 to selling agents in connection with this placement.

On August 16, 2010, Synergy entered into a securities purchase agreement with an accredited investor to sell securities and raise gross proceeds of $400,000 in a private placement. The Company sold 49,383 units to the investor with each unit consisting of one share of the Company's common stock and one warrant to purchase one additional share of the Company's common stock. The purchase price paid by the investor was $8.10 for each unit. The warrants expire after five years and are exercisable at $8.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On July 13, 2010 and October 12, 2010 Synergy issued 670,933 shares of its common stock as consideration for an agreement by certain holders of the Company's common stock to extend their lock-up of such shares from August 15, 2010 to January 15, 2011 or enter into a lock-up agreement until such date, as the case may be. This issuance was approved by the Company's Board of Directors on June 22, 2010 and represents 5% of the shares of previously issued common stock currently subject to a lock-up agreement or being requested to lock-up, as the case maybe. The fair value of the common stock issued to accomplish this lock-up extension totaled $3,235,040, based on the estimated fair value of the shares issued in connection with the June 30, 2010 and October 6, 2010 registered direct offerings. The par value of these shares was charged to additional paid in capital as a cost of facilitating the June 30, 2010 registered direct offering.

On October 1, 2010 the Company entered into a securities purchase agreement with an investor and raised gross proceeds of $2,500,000 in a registered direct offering. The Company paid a fee of $50,000 to a non-U.S. selling agent. The Company sold to the investor 500,000 shares of its common stock and warrants to purchase 200,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investor was $5.00 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On October 18, 2010 the Company entered into a securities purchase agreement with certain investors and raised gross proceeds of $1,525,000 in a registered direct offering. The Company paid a fee of $91,000 to a non-U.S. selling agent. The Company sold 305,000 shares of its common stock and warrants to purchase 122,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and two-fifths of a warrant to purchase a share of common stock. The purchase price paid by the investors was $5.00 for each unit. The warrants expire after five years and each whole warrant has an exercise price of $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On March 4, 2011, Synergy closed a registered direct offering with a non-U.S. investor which raised gross proceeds of $1,800,000. Synergy issued to the investor 300,000 shares of its common stock and warrants to purchase 210,000 shares of common stock. The purchase price paid by the investor was $6.00 for each unit. The warrants expire after seven years and are exercisable at $6.20 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

From May 2 to May 23, 2011, Synergy entered into securities purchase agreements with certain investors to raise gross proceeds of $2,499,999 in a registered direct offering. The Company issued to the investors 416,667 shares of its common stock and warrants to purchase

416,667 shares of common stock. The purchase price paid by the investors was $6.00 for each unit. The warrants expire after seven years, are exercisable at $4.25 per share and the exercise price is protected, in the event of subsequent equity sales at a lower price, for a period of two years from issuance. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis. These liabilities in the amount of $725,000 were reclassified on December 19, 2011 to additional paid in capital.

On June 3, 2011, a Synergy warrant holder exercised his warrants and purchased a total of 80,000 shares of common stock. Synergy raised gross proceeds of $415,309 as a result of the warrant exercise. The purchase price paid by the warrant holder was $5.00 for 49,383 shares and $5.50 for 30,617 shares. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy had determined that the warrants exercised in connection with this transaction were derivative liabilities when issued and the Company had been marking this liability to market at the end of each reporting period. Upon the exercise of these warrants the fair value of the related derivative liability totaling $486,328 was reclassified to Additional Paid in Capital.

From June 3 to June 15, 2011, Synergy entered into securities purchase agreements with certain investors to raise gross proceeds of $1,161,243 in a private placement. The Company issued to the investors 193,541 shares of its common stock and warrants to purchase 193,541 shares of common stock. The purchase price paid by the investors was $6.00 for each unit. The warrants expire after seven years and are exercisable at $6.50 per share. In connection with this transaction Synergy entered into a registration rights agreement with each of the investors pursuant to which Synergy agreed to register the shares of common stock and shares of common stock underlying the warrants in a resale registration statement to be filed within 45 days after the final closing of the private placement.

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy had determined that the warrants issued in connection with this private placement must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis. On December 19, 2011Synergy filed a registration statement on Form S-3 covering the 193,541shares of common stock and the 193,541 shares of common stock issuable upon exercise of the above warrants. This registration removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants of $315,901 on December 19, 2011 was reclassed from liability to additional paid in capital to equity.

On July 11, 2011, Synergy entered into a securities purchase agreement with an investor to raise gross proceeds of $242,750 in a private placement. The Company issued to the investor 40,458 shares of its common stock and warrants to purchase 40,458 shares of common stock. The purchase price paid by the investors was $6.00 for each unit. The warrants expire after seven years and are exercisable at $6.50 per share. In connection with this transaction Synergy entered into a registration rights agreement with the investor pursuant to which Synergy agreed to register the shares of common stock and shares of common stock underlying the warrants in a resale registration statement to be filed within 45 days after the final closing of the private placement. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that the warrants issued in connection with this private placement must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis. On December 19, 2011 Synergy filed a registration statement on Form S-3 covering the 40,458 shares of common stock and the 40,458 shares of common stock issuable upon exercise of the above warrants. This registration removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the derivative liability associated with these warrants of $73,931 was reclassed from liability to additional paid in capital.

On July 28, 2011, Synergy entered into a securities purchase agreement with certain investors to raise gross proceeds of $2,336,472 in a registered direct offering. The Company issued to the investors 333,782 shares of its common stock. The purchase price paid by the investors was $7.00 for each share of common stock and there were no warrants issued in connection with this transaction. On December 7, 2011 Synergy issued to these investors an additional 215,981 shares of common stock which make whole brought the purchase price per share paid by these investors to $4.25 per share.

On October 4, 2011, Synergy entered into a securities purchase agreement with certain investors for the sale of 552,647 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. Our gross proceeds from the sale of the units were $2,348,723. The purchase price paid by the investors was $4.25 per unit. The warrants expire after five years and are exercisable at $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

The October 4, 2011 transaction pricing resulted in the exercise price of the 416,667 warrants issued during May 2011 (the "May Warrants") to be reduced to $4.25 per share. No other outstanding warrants or common stock were affected by this subsequent equity sale at a lower price. The "price protection" rights attributable to the May Warrants remain in effect until the Company's listing on NASDAQ, December 1, 2011. This exercise price reduction from $6.50 per share to $4.25 per share decreased the prospective exercise proceeds attributable to the May Warrants by $937,500.

On October 19, 2011, Synergy entered into securities purchase agreements with various investors for the sale of 136,912 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The gross proceeds from the sale of the Units were $581,876. The purchase price paid by the investors was $4.25 per Unit. The Warrants expire after five years and are exercisable at $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC

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Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis. Synergy was listed on NASDAQ on December 1, 2011. This listing removed the condition which required these warrants to be treated as derivative liabilities.

On October 28, 2011, we entered into securities purchase agreements with various investors for the sale of 117,647 units in a registered direct offering, with each unit consisting of one share of common stock and one warrant to purchase 0.5 shares of common stock. The gross proceeds to us from the sale of the Units were $500,000. The purchase price paid by the investors was $4.25 per Unit. The Warrants expire after five years and are exercisable at $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance due to price protection features and marked to market on a quarterly basis. Synergy was listed on NASDAQ on December 1, 2011. This listing removed the condition which required these warrants to be treated as derivative liabilities

The October warrants relating to the 2011 fundraising in the amount of $593,296 were reclassed from liabilities to additional paid in capital upon listing of the NASDAQ.

On November 14, 2011, Synergy entered into a securities purchase agreement with certain accredited investors for the sale of 1,328,941 units in a private placement, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock. The gross proceeds from the sale of the Units were $5,648,000. The purchase price paid by the investors was $4.25 per Unit. The Warrants expire after five years and are exercisable at $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the investor warrants issued in connection with this Financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

On December 1, 2011, we entered into an underwriting agreement for the public offering and sale of 1,875,000 units, consisting of two shares of common stock and one warrant to purchase one share of common stock. On December 6, 2011 Synergy closed the offering at a price of $8.00 per unit, resulting in gross proceeds to the Company of $15,000,000. Each warrant has an exercise price of $5.50 per share and will expire five years from the date of issuance. Synergy also granted the Underwriters, under the terms of the Underwriting Agreement, an option to purchase up to an additional 281,250 units to cover over-allotments. On December 15, 2011 the over-allotment option was exercised for additional gross proceeds of $2,250,000. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that warrants issued in connection with this Financing transaction were not derivative liabilities.

On December 6, 2011, in connection with this underwritten financing, Synergy issued a total of 112,500 common stock purchase options to the underwriters and several principals of the firm. The Options expire three years from issuance and have an exercise price of $5.00 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" Synergy has determined that the warrants issued in connection with this Financing transaction were not derivative liabilities.

For the twelve months ended December 31, 2011, Synergy paid $2,148,383 in selling agent fees and legal expenses related to the above financing transactions and issued 9,025 warrants to a selling agent which expire after seven years and are exercisable at $6.50 per share, and 77,750 units consisting of one share of common stock and one warrant to purchase one share of common stock, which expire in five years, and are exercisable at $5.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that 8,025 warrants issued to selling agents were equity instruments upon issuance and 78,750 warrants must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

During the twelve months ended December 31, 2011, Synergy issued a total of 79,000 shares of common stock in payment for legal, consulting and scientific advisory services rendered. The fair value of these shares totaled $341,295 which amount has been reflected in our statement of operations for the year ended December 31, 2011.

On January 29, 2012 Synergy issued 26,272 unregistered shares of common stock to its corporate counsel for professional services rendered. The shares had a fair value on the date of issuance of $3.53 per share and $92,663 was recorded as legal expense during the year ended December 31, 2012.

On February 14, 2012, Synergy entered into an agreement and plan of merger (the "Agreement") with its wholly-owned subsidiary, Synergy Pharmaceuticals Inc., a Delaware corporation ("Synergy-DE") for the purpose of changing the state of incorporation of the Company to Delaware from Florida. Pursuant to the Agreement, the Company merged with and into Synergy-DE with Synergy-DE continuing as the surviving corporation. The directors and officers in office of the Company upon the effective date of the merger shall be the directors and officers of Synergy-DE, all of whom shall hold their directorships and offices until the election and qualification of their respective successors or until their tenure is otherwise terminated in accordance with the by-laws of Synergy-DE. The effective date of the merger was the date on which the Certificate of Merger is filed with the Secretary of State of Delaware and the Secretary of State of Florida. The Certificate of Merger was filed with the Secretary of State of Florida on February 15, 2012 and with the Secretary of State of Delaware on February 16, 2012.

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On May 9, 2012, Synergy closed an underwritten public offering of 10,000,000 shares of common stock at an offering price of $4.50 per share. The gross proceeds from this offering were $45 million, before deducting underwriting discounts and commissions and other estimated offering expenses of $2,952,930. Synergy also granted the underwriters a 45-day option to purchase up to an additional 1,500,000 shares of common stock at an offering price of $4.50 per share to cover over-allotments, if any. On June 6, 2012 the underwriters exercised the over-allotment option resulting in additional gross proceeds of $6,750,000, before deducting underwriting discounts, commissions and other offering expenses of $405,000, bringing total gross proceeds from the offering to $51,750,000.

On June 21, 2012, Synergy entered into a controlled equity sales agreement with a placement agent ("Agent") and agreed that Synergy may issue and sell through the Agent, up to $30,000,000 of common stock of the Company. From October 8, 2012 through December 31, 2012, Synergy sold 815,654 shares of common stock with gross proceeds of $4,111,802, at an average selling price of $5.04 per share. Selling agent fees totaled $123,385 on these sales. Synergy incurred $10,000 to attorneys' fee in connection with this transaction.

On January 15, 2013, the number of authorized shares of common stock increased from 100,000,000 to 200,000,000.

Synergy - Callisto Merger

On July 20, 2012, Synergy entered into an Agreement and Plan of Merger (the "Merger Agreement") with Callisto. Pursuant to the Merger Agreement, following the satisfaction or waiver of each of the applicable conditions set forth in the Merger Agreement, we and Callisto will merge (the "Merger"), whereupon Callisto's separate corporate existence will cease and we will continue as the surviving corporation of the Merger. Callisto was our largest shareholder and a development stage biopharmaceutical company.

On October 15, 2012, Synergy entered into Amendment No. 1 to the above Agreement and Plan of Merger, dated July 20, 2012 with Callisto. Pursuant to the Amendment, the parties agreed to, among other things, (i) increase the exchange ratio from .17 to .1799 and (ii) change the lock-up provision such that each share of our common stock received in connection with the Merger shall be subject to a lock-up beginning on the effective date of the Merger and ending on the earlier of (i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the Merger Agreement), or (iii) our written consent, at our sole discretion, provided our consent shall apply to all shares of our common stock issued pursuant to the Merger.

On July 23, 2012, Synergy paid $207,905 and on October 16, 2012, Synergy paid $74,945, to an investment bank in regards to a fairness opinion, from a financial point of view, of the Synergy shares to be issued to Callisto shareholders, in connection with the Merger with Callisto. These costs were reflected in Synergy's statement of changes in stockholder's equity/ (deficit) as costs of capital during the twelve months ended December 31, 2012.

The consummation of the Merger was subject to various customary closing conditions, including but not limited to, (i) approval by Callisto's and our stockholders, (ii) the Registration Statement on Form S-4 shall have been declared effective by the SEC and (iii) the shares of our common stock to be issued in the Merger shall have been approved for listing on The NASDAQ Capital Market. As of January 15, 2013, all of these conditions were met.

On January 17, 2013, we completed our acquisition of Callisto Pharmaceuticals, pursuant to the Merger Agreement. As a result of the Merger, each outstanding share of Callisto common stock was converted into the right to receive 0.1799 of one share of our common stock and the 22,295,000 shares of our common stock held by Callisto were canceled. In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by us and converted into a stock option to purchase the number of shares of our common stock that the holder would have received if such holder had exercised such stock option for shares of Callisto common stock prior to the Merger and exchanged such shares for shares of the Company's common stock in accordance with the Exchange Ratio. In addition, each Callisto stock option exercisable for shares of our common stock outstanding on January 17, 2013 was assumed by us and each outstanding warrant or obligation to issue a warrant to purchase shares of Callisto common stock, whether or not vested, was cancelled. Upon consummation of the Merger the related party balance due from Callisto, $3,305,636 as of December 31, 2012, was eliminated. In connection with the consummation of the Merger, we issued a total of approximately 28,605,354 shares of its common stock to former Callisto stockholders in exchange for their shares of Callisto common stock.

As Callisto does not meet the input, process and output definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of us, effected through exchange of Callisto shares for our shares, and the cancellation of our shares held by Callisto. The excess of our shares issued to Callisto shareholders over our shares held by Callisto is the result of a discount associated with the restricted nature of our shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. Upon the effective date of the Merger, we will account for the merger by assuming Callisto's net liabilities, of approximately $1.7 million. Our financial statements will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

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4. Accounting for Shared-Based Payments

Stock Options

ASC Topic 718 *"Compensation—Stock Compensation"* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way Synergy accounts for non-employee stock-based compensation. Synergy continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 "Equity *-Based Payment to Non-Employees"* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

Synergy adopted the 2008 Equity Compensation Incentive Plan (the "Plan") during the quarter ended September 30, 2008. Stock options granted under the Plan typically vest after three years of continuous service from the grant date and have a contractual term of ten years. Synergy did not issue stock options prior to the quarter ended September 30, 2008. On January 17, 2013, Synergy amended its 2008 Equity Compensation Incentive Plan and increased the number of shares of its common stock reserved for issuance under the Plan from 7,500,000 to 15,000,000.

Stock-based compensation expense related to Synergy options and restricted stock units have been recognized in operating results as follows:

	Years Ended December 31,			November 15, 2005 (inception) to
	2012	2011	2010	December 31, 2012
	(dollars in thousands)			

Employees—included in research and development	$ 975	$ 107	$ 188	$ 1,602
Employees—included in general and administrative	635	93	210	1,409
Subtotal employee stock based compensation	1,610	200	398	3,011
Non-employees—included in research and development	128	73	52	296
Non-employees—included in general and administrative	777	549	262	2,177
Subtotal non-employee stock based compensation	905	622	314	2,473
Total stock-based compensation expense	$ 2,515	$ 822	$ 712	$ 5,484

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions during the year ended December 31, 2012.

	Years Ended December 31,		
	2012	**2011**	**2010**
Risk-free interest rate	0.85%-1.5%	0.88%-1.25%	2.31%-2.71%
Dividend yield	—	—	—
Expected volatility	60%	70%	90%
Expected term (in years)	6.0 yrs.	6.0 yrs.	6.0 yrs.

Risk-free interest rate —Based on the daily yield curve rates for U.S. Treasury obligations with maturities which correspond to the expected term of the Company's stock options.

Dividend yield —Synergy has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Expected volatility —Based on the historical volatility of Synergy stock and management's estimate.

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Expected term —Synergy has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* , ("SAB No. 107"), which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Under SAB No. 107, options are considered to be "plain vanilla" if they have the following basic characteristics: (i) granted "at-the-money"; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, ("SAB No. 110"). SAB No. 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of "plain vanilla" share options in accordance with ASC Topic 718. The Company will continue to use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB No. 107, as amended by SAB No. 110. For the expected term, the Company has "plain-vanilla" stock options, and therefore used a simple average of the vesting period and the contractual term for options granted subsequent to January 1, 2006 as permitted by SAB No. 107.

Forfeitures —ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Synergy estimated future unvested option forfeitures based on its historical experience.

The weighted-average fair value per share of all options granted for the years ended December 31, 2012, 2011 and 2010 estimated as of the grant date using the Black-Scholes option valuation model was $2.38, $2.09 and $6.77 per share, respectively.

The unrecognized compensation cost related to non-vested employee stock options outstanding at December 31, 2012 was approximately $ 9,201,000. The December 31, 2012 balance is expected to be recognized over a weighted-average remaining vesting period of approximately 3 years.

On March 1, 2010, a majority of our shareholders acting by written consent approved an amendment to the Plan increasing the number of shares reserved under the Plan to 7,500,000 shares, after a retroactive change of a one for two (1:2) reverse stock split effective on November 30, 2011.

On January 17, 2013, Synergy amended its 2008 Equity Compensation Incentive Plan and increased the number of shares of its common stock reserved for issuance under the Plan from 7,500,000 to 15,000,000. As of December 31, 2012 there were no stock options outstanding under the Plan and no stock options available for future issuance under the Plan.

A summary of stock option activity and of changes in stock options outstanding under Synergy's plans is presented below:

	Number of	Exercise Price	Weighted Average Exercise Price	Intrinsic Value

	Options(1)	Per Share	Per Share	(in thousands)
Balance outstanding, January 1, 2010	2,107,008	$ 0.50-1.90	$ 0.61	$ 22,320
Granted (2)	2,232,500	$ 1.40	$ 1.40	
Exercised	—	—	—	
Forfeited	(37,500)	$ 1.40	$ 1.40	
Balance outstanding, January 1, 2011	4,302,008	$ 0.50-1.90	$ 1.04	$ 25,763
Granted	1,807,000	$ 3.35-4.30	$ 3.50	
Exercised	—	—	—	
Forfeited	(144,969)	$ 0.50-1.40	$ 1.04	
Balance outstanding, December 31, 2011	5,964,039	$ 0.50-4.30	$ 1.77	$ 6,027
Granted	3,875,229	$ 3.40-5.20	$ 4.29	
Exercised	—	—	—	
Forfeited	(105,000)	$ 3.40-4.38	$ 4.10	
Balance outstanding, December 31, 2012	9,734,268	$ 0.50-5.20	$ 2.75	$ 24,482
Exercisable at December 31, 2012	2,726,302	$ 0.50-5.20	$ 1.42	$ 10,464

(1) Number of shares outstanding represented above reflect a retroactive change of a one for two (1:2) reverse stock split effective on November 30, 2011.

(2) Contingent vesting upon change of control. The Fair Value at the date of grant was approximately $30,244,000 determined using the Black-Scholes option valuation model assumptions discussed above. No stock based compensation expense associated with these options was recognized since the grant date.

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Synergy's accumulated deficit position, no excess tax benefits have been recognized. Synergy accounts for common stock, stock options, and warrants granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield, at the grant date.

5. Income Taxes

At December 31, 2012, Synergy-DE has net operating loss carry forwards ("NOLs") aggregating approximately $94 million, which, if not used, expire beginning in 2013 through 2032. The utilization of these NOLs is subject to limitations based on past and future changes in ownership of Synergy pursuant to Internal Revenue Code Section 382. The Company has determined that ownership changes have occurred for Internal Revenue Code Section 382 purposes and therefore, the ability of the Company to utilize its NOLs is limited. The Company has no other material deferred tax items. Synergy records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the substantial doubt related to Synergy's ability to continue as a going concern and utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2012. As a result of this valuation allowance there are no income tax benefits reflected in the accompanying consolidated statements of operations to offset pre-tax losses.

The provisions of FASB ASC Topic 740-10-30-7, *Accounting for Income Taxes* were adopted by Synergy on January 1, 2007 and had no effect on Synergy's financial position, cash flows or results of operations upon adoption, as Synergy did not have any unrecognized tax benefits. Synergy's practice is to recognize interest and/or penalties related to income tax matters in income tax expense and none have been incurred to date.

Synergy has no uncertain tax positions subject to examination by the relevant tax authorities as of December 31, 2012. Synergy files U.S. and state income tax returns in jurisdictions with varying statutes of limitations. The 2009 through 2012 tax years generally remain subject to examination by federal and most state tax authorities.

On July 14, 2008, Synergy engaged in a tax-free reorganization pursuant to the Internal Revenue Code Section 368(a)(1)(B) thereby acquiring 100% of shares in Synergy-DE, from Callisto, , and other restricted holders of Synergy-DE shares, in exchange for 22,732,380 shares of the Company's common stock (or approximately 70% of the Company's outstanding common stock). The transaction was characterized as a tax-free type "B" reorganization resulting in no gain or loss recognition to the Company, for federal tax purposes.

Synergy periodically files for and receives certain federal, state and local research and development tax credits. The following are reported as other income in the Company's statement of operations for the years indicated: ($ in thousands)

Federal Qualifying Therapeutic	New York State	New York City

Year	Discovery Project	QETC Credit	Biotechnology Tax Credit	Total
2010	$ 244	—	$ 250	$ 494
2011	—	246	116	362
2012	—	256	250	506
Total	$ 244	$ 502	$ 616	$ 1,362

6. Commitments and Contingencies

Employment and Consulting Agreements

Gary S. Jacob, Ph.D.

On December 28, 2012, Dr. Gary Jacob, Chief Executive Officer and President entered into a new employment agreement with Synergy. This agreement is substantially similar to the previous Synergy employment agreement that was entered into on May 2, 2011, except, among

other things, the base salary for Dr. Jacob is $425,000 and the term of this agreement begins on January 1, 2013 and ends on December 31, 2016.

Dr. Jacob is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Dr. Jacob is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or enter into a joint venture in which we contribute such rights to the joint venture where the enterprise value equals or exceeds a minimum of $250 million in the term of the agreement or the license fees we contract to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or the sum of the license fees actually received in the case of an out license, multiplied by 0.5%. In addition, in the event we engage in a merger transaction or a sale of substantially all of our assets where (i) our enterprise value at the time of the merger or sale equals or exceed $400 million and our stockholders prior to consummation of the merger or sale beneficially own less than 20% of the stock of the surviving entity after consummation of the merger or (ii) our enterprise value at the time of the merger or sale or 12 months after the merger or sale equals or exceed $250 million and our stockholders prior to consummation of the merger or sale beneficially own 20% or more of the stock of the surviving entity after consummation of the merge, Dr. Jacob shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

If the employment agreement is terminated by Synergy other than for cause or as a result of Dr. Jacob's death or permanent disability or if Dr. Jacob terminates his employment for good reason which includes a change of control, Dr. Jacob shall receive (i) a severance payment equal average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base salary during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of compensation earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination.

Gabriele M. Cerrone

On December 28, 2012, Gabriele Cerrone, our Chairman, entered into a new consulting agreement with Synergy. This agreement is substantially similar to the previous consulting agreement that was entered on May 2, 2011, except, among other things, the base consulting fee for Mr. Cerrone is $425,000 and the term of this agreement begins on January 1, 2013 and ends on December 31, 2016.

Mr. Cerrone is eligible to receive a cash bonus of up to 50% of his base consulting fee per year based on meeting certain performance objectives and bonus criteria. Mr. Cerrone is also eligible to receive a realization bonus in the event that we enter into an out-license agreement for our technology or enter into a joint venture in which we contribute such rights to the joint venture where the enterprise value equals or exceeds a minimum of $250 million during the term of the agreement or the license fees we contract to receive equals or exceeds $50 million. The realization bonus will be equal to the enterprise value in the case of a joint venture or financing or the sum of the license fees actually received multiplied by 0.5%. In addition, in the event we engage in a merger transaction or a sale of substantially all of our assets where (i) our enterprise value at the time of the merger or sale equals or exceed $400 million and our stockholders prior to consummation of the merger or sale beneficially own less than 20% of the stock of the surviving entity after consummation of the merger or (ii) our enterprise value at the time of the merger or sale or 12 months after the merger or sale equals or exceed $250 million and our stockholders prior to consummation of the merger or sale beneficially own 20% or more of the stock of the surviving entity after consummation of the merge, Mr. Cerrone shall receive a bonus in an amount determined by multiplying the enterprise value by 2.5%.

On October 6, 2010 we achieved the $20 million threshold required for Mr. Cerrone's realization bonus to be accrued on the cumulative gross proceeds of financing transactions since August 1, 2008. This bonus totaled $1,211,912, was deemed compensatory in nature and charged to expense during the year ended December 31, 2010. Mr. Cerrone agreed with Synergy to defer payment of his bonus until the earlier of (i) March 31, 2012, (ii) the completion of a financing transaction yielding gross proceeds of $30 million on a cumulative basis subsequent to October 6, 2010 or (iii) the tenth business day after termination of the consulting agreement without cause or good reason (including a termination following a "change of control" transaction as that term is defined in his consulting agreement). In consideration of Mr. Cerrone agreeing to permit Synergy to defer payment of his bonus Synergy agreed to indemnify him from any liability for taxes or penalties that he may incur pursuant to Section 409A of the Internal Revenue Code and comparable state income tax laws. This bonus was paid in full during the twelve months ended December 31, 2011, which payment does not terminate the Company's indemnification liability.

If the consulting agreement is terminated by Synergy other than for cause or as a result of Mr. Cerrone's death or permanent disability or if Mr. Cerrone terminates the agreement for good reason which includes a change of control, Mr. Cerrone shall receive (i) a severance payment equal to the higher of the aggregate amount of his base consulting fee for the then remaining term of the agreement or twelve times the average monthly base consulting fee paid or accrued during the three full calendar months preceding the termination, (ii) expense compensation in an amount equal to twelve times the sum of his average base consulting fee during the three full months preceding the termination, (iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iv) payment in respect of consulting fees and bonus earned but not yet paid and (v) payment of the cost of medical insurance for a period of twelve months following termination.

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Bernard F. Denoyer

On January 20, 2011, Bernard F. Denoyer entered into an executive employment agreement with Synergy in which he agreed to serve as Senior Vice President, Finance. The term of the agreement was effective as of January 20, 2011, continues until January 20, 2012 and is automatically renewed for successive one year periods at the end of each term. Mr. Denoyer's base salary is currently $200,850 as of December 31, 2012 and $215,000 effective January 1, 2013. He is eligible to receive a cash bonus of up to 25% of his base salary per year at the discretion of the Compensation Committee of the Board of Directors. If the employment agreement is terminated by Synergy other than for cause or as a result of Mr. Denoyer's death or permanent disability or if Mr. Denoyer terminates his employment for good reason which includes a change of control, Mr. Denoyer shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iii) payment in respect of compensation earned but not yet paid and (iv) payment of the cost of medical insurance for a period of twelve months following termination.

Kunwar Shailubhai

On June 25, 2012, Kunwar Shailubhai entered into an amended and restated employment agreement with us, which amended his previous agreement dated April 6, 2004. In his new agreement, Mr. Shailubhai agreed to serve as Chief Scientific Officer and Executive Vice President. The term of the agreement continues until June 25, 2014 and is automatically renewed for successive one year periods at the end of each term. Mr. Shailubhai's base salary is currently $250,000 as of December 31, 2012 and $270,000 effective January 1, 2013. He is eligible to receive a cash bonus of up to 30% of his base salary per year at the discretion of the Compensation Committee of the Board of Directors. If the employment agreement is terminated by Synergy other than for cause or as a result of Mr. Shailubhai's death or permanent disability or if Mr. Shailubhai terminates his employment for good reason which includes a change of control, Mr. Shailubhai shall receive (i) a severance payment equal to the higher of the aggregate amount of his base salary for the then remaining term of the agreement or twelve times the average monthly base salary paid or accrued during the three full calendar months preceding the termination, (ii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date, (iii) payment in respect of compensation earned but not yet paid and (iv) payment of the cost of medical insurance for a period of twelve months following termination.

Lease agreements

Synergy's corporate headquarters located at 420 Lexington Avenue, New York, was subject to a lease which has a monthly rate of $16,000 and expired on March 31, 2012. This facility was provided to Synergy under a space sharing arrangement with Callisto. On March 30, 2012 Synergy assumed the Callisto lease and extended this lease through March 31, 2014, at a monthly rate of approximately $19,000. On August 28, 2012 Synergy entered into a Lease Modification, Substitution of Space and Extension Agreement with SL Green Graybar Associates. Under the new lease we will be moving our corporate headquarters and clinical development offices to a larger office space on the 20th floor of 420 Lexington Avenue. The new lease has a monthly rate of approximately $35,000 and expires March 31, 2019. Synergy expects to move in first half of 2013.

Synergy also occupies a small laboratory and several offices in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease which expired August 31, 2011. On February 1, 2012 Synergy extended this lease through December 31, 2013, at a monthly rate of $2,800.

Clinical Research Organization arrangements

The Company may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory, and approval milestones. The specific timing of such milestones cannot be predicted and depends upon future discretionary clinical developments as well as regulatory agency actions which cannot be predicted with certainty (including action which may never occur). These additional contingent payments aggregate to approximately $19 million.

The following table is a summary of contractual obligations for the periods indicated that existed as of December 31, 2012.

	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases	$ 2,752	$ 532	$ 805	$ 1,301	$ 114
Purchase obligations—					

principally employment and consulting services(1)	6,060	1,971	2,792	1,297	—
Purchase Obligations—Major Vendors(2)	19,380	19,380	—	—	—
Total obligations	$ 28,192	$ 21,883	$ 3,597	$ 2,598	$ 114

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(1) Represents salary, bonus, and benefits for remaining term of employment agreements with Gary S. Jacob, CEO, Bernard F Denoyer, Senior Vice President, Finance, Kunwar Shailubhai, Chief Scientific Officer and consulting fees, bonus and benefits for remaining term of consulting agreement with Gabriele M. Cerrone, Chairman.

(2) Represents amounts that will become due upon future delivery of supplies, drug substance and test results from various suppliers, under open purchase orders as of December 31, 2012.

Litigation

On August 9, 2012, a purported stockholder class action complaint was filed in the Supreme Court for the State of New York, captioned Shona Investments v. Callisto Pharmaceuticals, Inc., et al., Civil Action No. 652783/2012. The complaint names as defendants, Callisto, each member of the Board of Callisto (the "***Individual Defendants*** ") and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. Callisto and Synergy believe the plaintiffs' allegations lack merit and will contest them.

On August 31, 2012, a purported stockholder class action complaint was filed in the Court of Chancery of the State of Delaware, captioned Gary Wagner v. Gary S. Jacob, Inc., et al., Case No. 7820-VCP. The complaint names as defendants, Callisto, the Individual Defendants and Synergy. The complaint generally alleges that the Individual Defendants breached their fiduciary duties and that Synergy aided and abetted the purported breaches of such fiduciary duties. The relief sought includes, among other things, an injunction prohibiting consummation of the proposed transaction, rescission (to the extent the proposed transaction has already been consummated) and the payment of plaintiffs' attorneys' fees and costs. Callisto and Synergy believe the plaintiffs' allegations lack merit and will contest them.

On or about November 2, 2012, counsel for the Delaware Plaintiff reached an agreement with Counsel for Plaintiff in the New York action by which the Plaintiffs from the two cases agreed to conduct preliminary injunctive proceedings and discovery related thereto in the New York action only, and during the pendency of which the plaintiff in the Delaware action would effectively stay any prosecution of its case. The parties have discussed the scope of preliminary discovery and document production.

There can be no assurance as to the outcome of these proceedings.

7. Research and Development Expense

Research and development costs include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, patient costs, drug formulation and tableting, data collection, monitoring and clinical trial insurance.

In accordance with FASB ASC Topic 730-10-55, Research and Development, Synergy recorded prepaid research and development costs of $926,380 as of December 31, 2012, as compared to $577,745 as of December 31, 2011, for nonrefundable pre-payments for production of drug substance, analytical testing services for its drug candidates, and clinical trials. In accordance with this guidance, Synergy expenses deferred research and development costs when drug compound is delivered and services are performed.

In addition, on August 17, 2012, Synergy signed an Asset Purchase Agreement with Bristol-Myers Squibb Company ("BMS") and acquired certain assets related to FV-100, an orally available nucleoside analog, currently being developed for the treatment of shingles, a severe, painful skin rash caused by reactivation of the varicella zoster virus — the virus that causes chickenpox. The terms of the Agreement provide for an initial base payment of $1 million, subsequent milestone payments covering (i) marketing (FDA) approval and (ii) on achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales.

The FV-100 assets acquired from BMS include (i) an exclusive license to the patent portfolio and (ii) all historical research and clinical study protocols, data and results. Both of these intangible assets enable Synergy to continue the clinical development in future trials and ultimately have the freedom to operate ("FTO") should FDA approval be achieved. Synergy believes the intangible assets purchased from BMS are limited exclusively to the future development of FV-100 for the treatment of shingles. ASC Topic 350-30-25-2(c) requires that the costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time the costs are incurred. Accordingly, Synergy charged the $1,000,000 base payment to purchased in-process research and development expense during the twelve months ended December 31, 2012.

8. Derivative Financial Instruments

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, “Derivatives and Hedging: Contracts in Entity’s Own Equity” (“ASC Topic 815-40”). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity’s own stock, which would qualify as a scope exception under ASC Topic 815-10.

Based upon the Company’s analysis of the criteria contained in ASC Topic 815-40, Synergy has determined that certain warrants issued in connection with sale of our common stock in the year ended December 31, 2012 and prior years must be classified as derivative instruments. In accordance with ASC Topic 815-40, these warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company’s statement of operations. The Company estimates the fair value of certain warrants using the Black-Scholes option pricing model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at each period end during the twelve months ended December 31, 2012 and December 31, 2011 were:

	Year ended December 31, 2012	Year ended December 31, 2011
Fair value of Synergy common stock	$4.05-$5.26	$3.50 - $9.04
Expected warrant term	5-7 years	4-7 years
Risk-free interest rate	0.23%-1.33%	0.36% - 2.22%
Expected volatility	60%	70%-90%
Dividend yield	0%	0%

Estimated fair value of stock is the closing market price of the Company’s common stock on the date of warrant issuance and end of each reporting period the derivative instruments are marked to market. Expected volatility is based on historical volatility of Synergy’s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants. Expected volatility is based on historical volatility of the Company’s common stock.

Certain of Synergy’s warrants issued during the twelve months ended December 31, 2012 contained a price protection clause which variable exercise price required the Company to use a binomial model to determine fair value. The range of assumptions used to determine the fair value of the warrants at each period end during the twelve months ended December 31, 2012 was as follows:

	Year ended December 31,	
	2012	2011
Estimated fair value of Synergy common stock	$3.28-$4.53	$2.71-$5.02 (*)
Expected warrant term	4.13-4.63 years	5-7 years
Risk-free interest rate	0.62%-1.04%	0.90%-2.64%
Expected volatility	60%	70%-90%
Dividend yield	0%	0%

(*) Restated for 1:2 reverse stock split effective November 30, 2011.

In the Binomial model, the assumption for estimated fair value of the stock is the closing market price of the Company’s common stock on the date of warrant issuance and end of each reporting period the derivative instruments are marked to market, adjusted for small discounts experienced in recent registered direct offerings. Expected volatility is based on historical volatility of Synergy’s common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Synergy used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

The following table sets forth the components of changes in the Synergy’s derivative financial instruments liability balance for the periods indicated:

Date	Description	Warrants	Derivative Instrument Liability (in thousands)
12/31/2010	Balance of derivative financial instruments liability	728,469	$ 3,487
3/31/2011	Fair value of new warrants issued during the quarter	210,000	1,313
3/31/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	339
3/31/2011	Balance of derivative financial instruments liability	938,469	5,139

6/30/2011	Fair value of new warrants issued during the quarter	611,207	2,608
6/30/2011	Exercise of warrants during the quarter	(80,000)	(486)
6/30/2011	Change in fair value of warrants during the quarter recognized as other expense in the statement of operations	—	698
6/30/2011	Balance of derivative financial instruments liability	1,469,676	7,959
9/30/2011	Fair value of new warrants issued during the quarter	40,458	285
9/30/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations	—	(4,383)
9/30/2011	Balance of derivative financial instruments liability	1,510,134	3,861
12/31/2011	Fair value of new warrants issued during the quarter	1,810,294	3,082
12/31/2011	Reclass of derivative liability to equity during the quarter	(1,055,268)	(1,707)
12/31/2011	Change in fair value of warrants during the quarter recognized as other income in the statement of operations	—	(1,911)
12/31/2011	Balance of derivative financial instruments liability	2,265,160	3,325
3/31/2012	Fair value of new warrants issued during the quarter	—	—
3/31/2012	Change in fair value of warrants during the quarter	—	(8)
3/31/2012	Balance of derivative financial instruments liability	2,265,160	3,317
6/30/2012	Warrants classified to derivative liability during quarter	112,500	169
6/30/2012	Change in fair value of warrants during the quarter	—	1,317
6/30/2012	Balance of derivative financial instruments liability	2,377,660	4,803
9/30/2012	Fair value of new warrants issued during the quarter	—	—
9/30/2012	Change in fair value of warrants during the quarter	—	(140)
9/30/2012	Balance of derivative financial instruments liability	2,377,660	4,663
12/31/2012	Fair value of new warrants issued during the quarter	—	—
12/31/2012	Change in fair value of warrants during the quarter	—	764
12/31/2012	Reclass of derivative liability to equity during the quarter	(112,500)	(169)
12/31/2012	Balance of derivative financial instruments liability	2,265,160	$ 5,258

(1) Number of warrants outstanding represented above reflect a retroactive effect of a one for two (1:2) reverse stock split effective on November 30, 2011.

9. Fair Value Measurements

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2011 and December 31, 2012:

($ in thousands)

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2011	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2012
Derivative liabilities related to Warrants	$ —	$ —	$ 3,325	$ 3,325	$ —	$ —	$ 5,258	$ 5,258

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the twelve months ended December 31, 2012 and December 31, 2011:

($ in thousands)

Balance at	Fair value of warrants exercised and reclassified to	Fair Value of	(Gain) or loss recognized in earning from	Balance as of	Fair Value of	(Gain) or loss recognized in earning from	Balance as of

Description	December 31, 2010	additional paid in capital	warrants upon issuance	Change in Fair Value	December 31, 2011	warrants upon issuance	Change in Fair Value	December 31, 2012
Derivative liabilities related to Warrants	$ 3,487	$ (2,193)	$ 7,288	$ (5,257)	$ 3,325	$ —	$ 1,933	$ 5,258

The gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

10. Property and Equipment

Property and equipment consists of leasehold improvements, which are recorded at cost. The Company will depreciate the costs when the property is placed into service, using the straight-line method over the remaining term of the underlying lease.

Property and equipment also includes laboratory, testing and computer equipment, and furniture and fixtures, which consist of office furniture. Both are stated at cost, with useful lives ranging from 2 - 5 years, depreciated on a straight line basis. Depreciation expense for the years ended December 31, 2012, 2011, 2010 and from November 15, 2005 (inception) to December 31, 2012 were approximately $2,000, $2,000, $2,000 and $10,000, respectively.

($ in thousands)

	December 31, 2012	December 31, 2011
Furniture and fixtures	$ 39	$ 39
Machinery and equipment	12	12
Leasehold improvement	26	—
Less accumulated depreciation	(47)	(45)
Property and equipment, net	$ 30	$ 6

11. Related Parties

As of December 31, 2012, Synergy's principal shareholder, Callisto, owns 34% of its outstanding shares.

As of December 31, 2012, Synergy had advanced Callisto $3,305,636, which is Callisto's share of Synergy payments for common operating costs since July 2008. This indebtedness is evidenced by an unsecured promissory note which bears interest at 6% per annum. Interest income earned on this note totaled approximately $148,000 and $84,000 during the twelve months ended December 31, 2012 and 2011, respectively.

As of December 31, 2012 and December 31, 2011, the balances due from Callisto Pharmaceuticals, Inc. are comprised of the following amounts:

($ in thousands)

	December 31, 2012	December 31, 2011
Rent, utilities, and property taxes	$ 123	$ 90
Insurance and other facilities related overhead	344	250
Independent accountants and legal	935	510
Financial printer and transfer agent fees	427	217
Salaries and consulting fees	344	289
Income Taxes	325	—
Merger fairness opinion	270	—
Working capital advances, net of repayments	538	186
Total due from Callisto	$ 3,306	$ 1,542

Upon consummation of the Merger the related party balances due from Callisto was eliminated and charged to Synergy's equity (See Note 3. above).

12. Quarterly Consolidated Financial Data (Unaudited)

	Quarter Ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012

	(dollars in thousands, except share and per share data)			
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
Research and Development	5,338	7,626	7,245	9,085
Purchased in-process research and development	—	—	1,000	—
General and administrative	1,732	1,919	1,843	2,447
Loss from operations	(7,070)	(9,545)	(10,088)	(11,532)
Other income	—	256	—	250
Interest and investment income	39	48	63	68
Change in fair value of derivative instruments —warrants	8	(1,317)	140	(764)
Total Other Income/ (Loss)	47	(1,013)	203	(446)
Net Loss	$ (7,023)	$ (10,558)	$ (9,885)	$ (11,978)
Weighted average common shares outstanding— basic and diluted	54,298,079	60,416,068	65,806,178	66,194,306
Net loss per Common Share, basic and diluted(a):	$ (0.13)	$ (0.17)	$ (0.15)	$ (0.18)

(a) Basic and diluted EPS are computed independently for each of the periods presented. Accordingly, the sum of the quarterly EPS amounts may not agree to the total for the year.

	Quarter Ended			
	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
	(dollars in thousands, except per share data)			
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
Research and Development	1,478	2,355	3,883	5,703
General and administrative	1,897	1,524	1,103	2,222
Loss from operations	(3,375)	(3,879)	(4,986)	(7,925)
Other income	—	—	—	362
Interest and investment income	24	20	20	26
Interest expense	(12)	—	—	—
Change in fair value of derivative instruments —warrants	(339)	(698)	4,383	1,911
Total Other Income/(Loss)	(327)	(678)	4,403	2,299
Net Loss	$ (3,702)	$ (4,557)	$ (583)	$ (5,626)
Weighted average common shares outstanding— basic and diluted (a)	46,167,416	46,642,901	47,308,946	48,657,013
Net loss per common share—basic and diluted(b):	$ (0.08)	$ (0.10)	$ (0.01)	$ (0.12)

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(a) Weighted average common shares outstanding represented above reflect a retroactive change of a one for two (1:2) reverse stock split effective on November 30, 2011.

(b) Basic and diluted EPS are computed independently for each of the periods presented. Accordingly, the sum of the quarterly EPS amounts may not agree to the total for the year.

13. Subsequent Events

On January 17, 2013, Synergy completed its acquisition of Callisto, pursuant to the Merger Agreement, as amended (see Note 3). As a result of the Merger, each outstanding share of Callisto common stock was converted into the right to receive 0.1799 of one share of Synergy common stock and the 22,295,000 shares of common stock held by Callisto were canceled. In addition, each stock option exercisable for shares of Callisto common stock that was outstanding on January 17, 2013 was assumed by Synergy and converted into a stock option to purchase the number of shares of Synergy's common stock that the holder would have received if such holder had exercised such stock option for shares of Callisto common stock prior to the Merger and exchanged such shares for shares of the Company's common stock in accordance with the Exchange Ratio. In addition, each Callisto stock option exercisable for shares of Synergy's common stock outstanding on January 17, 2013 was assumed by Synergy and each outstanding warrant or obligation to issue a warrant to purchase shares of Callisto common stock, whether or not vested, was cancelled.

In connection with the consummation of the Merger, Synergy issued a total of approximately 28,605,354 shares of its common stock to former Callisto stockholders in exchange for their shares of Callisto common stock. Each share of Synergy's common stock received in connection with the Merger will be subject to a lock-up beginning on January 17, 2013 and ending on the earlier of (i) twenty-four (24) months after such date, (ii) a Change in Control (as defined in the merger agreement), or (iii) written consent of Synergy, at Synergy's sole discretion, provided Synergy's consent shall apply to all shares issued pursuant to the Merger.

As Callisto does not meet the definition of a business under ASC 805, the merger will not be accounted for as a business combination. The merger is expected to be accounted for as a recapitalization of Synergy, affected through exchange of Callisto shares for Synergy shares, and the cancellation of Synergy shares held by Callisto. The excess of Synergy shares issued to Callisto shareholders over the Synergy shares held by Callisto is the result of a discount associated with the restricted nature of the Synergy shares to be received by Callisto shareholders. Therefore, considering this discount, the share exchange has been determined to be equal from a fair value stand point. Upon the effective date of the Merger, Synergy will account for the merger by assuming Callisto's net liabilities, of approximately $1.7 million. Synergy's financial statements will not be restated retroactively to reflect the historical financial position or results of operations of Callisto.

From January 1, 2013 through March 18, 2013, Synergy sold 758,093 shares of common stock with gross proceeds of $4,670,861, at an average selling price of $6.16 per share, pursuant to the June 2012 controlled equity sales agreement with a placement agent (footnote 3). Selling expenses totaled $140,126.

Exhibit 2.1

Exhibit 10.3

EXECUTIVE EMPLOYMENT AGREEMENT

This EXECUTIVE EMPLOYMENT AGREEMENT (the "Agreement") dated December 28, 2012 by and between Synergy Pharmaceuticals Inc., a company incorporated under the laws of Delaware (the "Company"), and Gary S. Jacob, Ph.D., an individual (the "Executive") with reference to the following facts:

WHEREAS, Executive serves as the President and Chief Executive Officer of the Company which is engaged in the business of developing and marketing drug products;

WHEREAS, the Executive has previously entered into an employment agreement with the Company as of March 11, 2009 , as amended by the Amended and Restated Employment Agreement with the Company as of February 10, 2010 and the Second Amended and Restated Employment Agreement with the Company as of May 2, 2011 (the "Prior Employment Agreement"); and

WHEREAS, the parties wish to enter into a new Agreement between the Executive and the Company in its entirety, on the terms and conditions contained in this Agreement, which will supersede the Prior Employment Agreement and all prior agreements and understandings between the parties, oral or written.

NOW THEREFORE, in consideration of the foregoing facts and mutual agreements set forth below, the parties, intending to be legally bound, agree as follows:

1. Employment. The Company hereby agrees to employ Executive, and Executive hereby accepts such employment and agrees to perform Executive's duties and responsibilities in accordance with the terms and conditions hereinafter set forth.

1.1 Duties and Responsibilities. Executive shall serve as Chief Executive Officer and President. During the Employment Term, Executive shall perform all duties and accept all responsibilities incident to such positions and other appropriate duties as may be assigned to Executive by the Company's Board of Directors (the "Board") from time to time. Executive shall also serve as a director of the Company if requested by the Board, and as an officer of one or more of the Company's subsidiaries without any additional compensation. The Company shall retain full direction and control of the manner, means and methods by which Executive performs the services for which he is employed hereunder and of the place or places at which such services shall be rendered. The Executive also agrees that in the absence of a Chief Accounting Officer, he will sign various federal and state securities filings as the Company's principal accounting officer.

1.2 Employment Term. The term of Executive's employment under this Agreement commences as of January 1, 2013 (the "Effective Date") and shall continue until December 31, 2016, unless earlier terminated in accordance with Section 4 hereof. The term of Executive's employment shall be automatically renewed for successive one (1) year periods until the Executive or the Company delivers to the

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other party a written notice of their intent not to renew the "Employment Term," such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective "Employment Term" as that term is defined below. The period commencing as of the Effective Date and ending December 31, 2016 or such later date to which the term of Executive's employment under the Agreement shall have been extended is referred to herein as the "Employment Term" and the end of the Employment Term is referred to herein as the "Expiration Date."

1.3 Extent of Service. During the Employment Term, Executive agrees to use Executive's best efforts to carry out the duties and responsibilities under Section 1.1 hereof and to devote substantially all Executive's business time, attention and energy thereto. Executive further agrees not to work either on a part-time or independent contracting basis for any other business or enterprise during the Employment Term without the prior written consent of the Board, which consent shall not be unreasonably withheld.

1.4 Base Salary. The Company shall pay Executive a base salary (the "Base Salary") at the annual rate of $425,000 (U.S.) payable at such times as the Company customarily pays its other senior level executives (but in any event no less often than monthly). The Base Salary shall be subject to all state, federal, and local payroll tax withholding and any other withholdings required by law. The Executive's Base Salary may be increased, but not decreased by the Board or the Compensation Committee of the Board (the "Compensation Committee") Once increased, such increased amount shall constitute the Executive's Base Salary and shall not be decreased.

1.5 Incentive Compensation.

(a) Bonus. Executive shall be eligible to earn a cash bonus of up to 50% of his Base Salary per full calendar year during the Employment Term based on meeting performance objectives and bonus criteria to be mutually identified by Executive and the Compensation Committee. Bonuses, if any, shall be subject to all applicable tax and payroll withholdings. The bonus shall be determined on or before March 1 of each year of the Employment Term commencing January 1, 2013 and paid on or before April 14 of each year.

(b) Realization Bonus.

(i) In the event during the Term of this Agreement the Company enters into either a out-license agreement for any of its technology that grants exclusive marketing rights to a third party (and the license fees the Company contracts to receive (disregarding any contingencies to such payment) equals or exceeds $50 million) or enters into a joint venture in which the Company contributes such rights to the joint venture, in each case where the Enterprise Value (defined below) equals or exceeds the minimum value of $250 million, the Company shall accrue a bonus determined by multiplying the Enterprise Value (defined below) in the case of a joint venture or the sum

of the license fees actually received in the case of an out license, as the case may be, by 0.5% (one half percent).

(ii) In the event during the Term of this Agreement the Company

(A) engages in (i) a merger transaction as a result of which the stockholders of the Company existing immediately before the consummation of such merger beneficially own less than 20% of the stock of the ultimate parent of the surviving entity immediately after the consummation of the merger, where the Enterprise Value equals or exceeds a minimum value of $400 million or (ii) a sale of substantially all of the assets of the Company, where the Enterprise Value equals or exceeds a minimum value of $400 million, the Executive shall accrue a bonus in an amount determined by multiplying the Enterprise Value by 2.5% (a "Sale Transaction"); or

(B) engages in (i) a merger transaction, as a result of which the stockholders of the Company existing immediately before the consummation of such merger beneficially own 20% or more of the stock of the ultimate parent of the surviving entity immediately after the consummation of the merger, where the Enterprise Value of the Company (either at the effective date of the transaction or 12 months after the effective date of the transaction) equals or exceeds a minimum value of $250 million or (ii) a sale of substantially all of the assets of the Company, where the Enterprise Value equals or exceeds a minimum value of $250 million, the Executive shall accrue a bonus in an amount determined by multiplying the Enterprise Value by 2.5% (a "Combination Transaction").

(iii) The accrued bonuses shall be payable to Executive (a) in the same form of the consideration received by the Company's stockholders in full contemporaneously at the closing of any joint venture, Sale Transaction or Combination Transaction; or (b) in cash 5 business days after the Company's receipt of license fees at the rate of 0.5% of license fees actually received. The expiration or termination of this Agreement shall not terminate or diminish the Executive's right to receive bonus payments with respect to out license fees collected or the consummation of any joint venture, Sale Transaction or Combination Transaction after the termination or expiration of this Agreement provided the Company has entered into an agreement for such a transaction any time during the Employment Term or 90 days thereafter.

(iv) The "Enterprise Value" in the case of a Change in Control in which consideration is payable to the Company in respect of its assets or business, shall mean the total cash and non-cash (including, without limitation, the assumption of debt) consideration received by the Company or in the case of a Change in Control in which consideration is payable to the Company's stockholders, the total cash and non-cash (including, without limitation, the assumption of debt) consideration payable to the Company's stockholders. "Enterprise Value" shall also include, if applicable, any cash or non-cash consideration payable to the Company or to the Company's stockholders on a

contingent, earnout or deferred basis. To the extent that any consideration in a transaction is not received in cash upon the consummation of the Change in Control, the value of such non-cash consideration for purposes of calculating the Enterprise Value will be determined by the independent Board of Directors of the Company prior to the Change in Control in good faith in consultation with an independent investment bank or financial advisor retained by Board of Directors in connection with the Change in Control transaction. In the event that less than 100% of the stock or assets of the Company is purchased in the Change in Control transaction, the Enterprise Value shall be extrapolated from the percentage of the Company's capital stock or assets impacted in such Change in Control transaction to determine if the applicable threshold was exceeded, but the Transaction Fee shall be calculated based on the actual consideration received by the Company or shareholders, as the case may be. Section 1.5(b), however, shall not apply to any event resulting in a Change in Control in which neither the Company nor its stockholders receives consideration either upon, or in connection with, the occurrence or consummation of the event resulting in a Change in Control.

(v) For purposes of Section 1.5(b)(ii)(B), Enterprise Value at any time subsequent to the effective date of a transaction shall be computed by reference to the market capitalization of the combined entity (based on an average closing price of the combined entities common stock for a period of 20 consecutive trading days) multiplied by the quotient of the number of combined entities shares of common stock and common stock equivalents issued to the Company's stockholders in the transaction divided by the total number of shares of the common stock and common stock equivalents outstanding on the effective date of the transaction, on a fully diluted basis.

(c) Options. The Compensation Committee will consider grants of options to the Executive no less frequently than annually commencing January 1, 2013.

(d) Executive Benefits. The Executive shall be entitled to participate in all executive benefit or incentive compensation plans now maintained or hereafter established by the Company for the purpose of providing compensation and/or benefits to executives of the Company and any supplemental retirement, salary continuation, stock option, deferred compensation, supplemental medical or life insurance or other bonus or incentive compensation plans. Unless otherwise provided herein, the Executive's participation in such plans shall be on the same basis and terms as other similarly situated executives of the Company. No additional compensation provided under any of such plans shall be deemed to modify or otherwise affect the terms of this Agreement or any of the Executive's entitlements hereunder.

1.6 Other Benefits. During the Employment Term, Executive shall be entitled to participate in all employee benefit plans and programs made available to the Company's senior level executives as a group or to its employees generally, as such plans or programs may be in effect from time to time (the "Benefit Coverages"), including, without limitation, medical, dental, hospitalization, short-term and long-term disability and life insurance plans, accidental death and dismemberment protection and travel accident insurance. Executive shall be

provided office space and staff assistance appropriate for Executive's position and adequate for the performance of his duties.

1.7 Reimbursement of Expenses; Vacation; Sick Days and Personal Days. Executive shall be provided with reimbursement of expenses related to Executive's employment by the Company on a basis no less favorable than that which may be authorized from time to time by the Board, in its sole discretion, for senior level executives as a group. Executive shall be entitled to vacation and holidays in accordance with the Company's normal personnel policies for senior level executives, but not less than three (3) weeks of vacation per calendar year, provided Executive shall not utilize more than ten (10) consecutive business days without the express consent of the Board of Directors. Unused vacation time will be forfeited as of December 31 of each calendar year of the Employment Term. Executive shall be entitled to no more than an aggregate of ten (10) sick days and personal days per calendar year.

1.8 No Other Compensation. Except as expressly provided in Sections 1.4 through 1.7, Executive shall not be entitled to any other compensation or benefits.

2. Confidential Information. Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Employment Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales techniques, strategy and programs, computer programs and software and financial information (collectively referred to as "Confidential Information"). Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Executive's duties for the Company and in a manner consistent with the Company's policies regarding Confidential Information. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Except as required in the performance of Executive's duties for the Company, or unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive

agrees to return immediately to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession. As a condition of Executive's continued employment with the Company and in order to protect the Company's interest in such proprietary information, the Company shall require Executive's execution of a Confidentiality Agreement and Inventions Agreement in the form attached hereto as Exhibit "B", and incorporated herein by this reference.

3. Non-Competition; Non-Solicitation.

3.1 Non-Compete. The Executive hereby covenants and agrees that during the term of this Agreement and for a period of one year following the end of the Employment Term, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, Executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any Competing Business in the Covered Area. For the purpose of this Section 3.1, (i) "Competing Business" means any biotechnology or pharmaceutical company, any contract manufacturer, any research laboratory or other company or entity (whether or not organized for profit) that has, or is seeking to develop, one or more products or therapies that is related to azaspiranes and guanylyl cyclase receptor agonists and (ii) "Covered Area" means all geographical areas of the United States and foreign jurisdictions where the Company then has offices and/or sells its products directly or indirectly through distributors and/or other sales agents. Notwithstanding the foregoing, the Executive may own shares of companies whose securities are publicly trades, so long as such securities do not constitute more than one percent (1%) of the outstanding securities of any such company.

3.2 Non-Solicitation. The Executive further agrees that as long as the Agreement remains in effect and for a period of one (1) year from its termination, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company.

3.3 Remedies. The Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and the Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by the Executive of his covenants and agreements set forth herein. Accordingly, the Executive agrees and acknowledges that any such violation or threatened violation of this Section 3 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in

law, in equity or otherwise, the Company and its affiliates shall be entitled to obtain injunctive relief against he threatened breach of this Section 3 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

4. Termination.

4.1 Termination Without Cause or for Good Reason.

(a) If this Agreement is terminated by the Company other than for Cause (as defined in Section 4.4 hereof) or as a result of Executive's death or Permanent Disability (as defined in Section 0 hereof), or if Executive terminates his employment for Good Reason (as defined in Section 0 hereof) prior to the Expiration Date, Executive shall receive or commence receiving as soon as practicable in accordance with the terms of this Agreement:

(i) a severance payment (the "Severance Payment"), which amount shall be paid in a cash lump sum within ten (10) days of the date of termination, in an amount equal to the higher of the aggregate amount of the Executive's Base Salary for the then remaining term of this Agreement or twelve times the average monthly Base Salary paid or accrued during the three full calendar months immediately preceding such termination;

(ii) expense compensation, which shall be paid in a lump sum payment within ten (10) days of the date of termination, in an amount equal to the higher of the aggregate amount of the sum of average monthly cost during the three full months immediately preceding such termination of Consultant's reimbursed expenses set forth in Section 1.7 for the then remaining term of this Agreement or twelve times the sum of average monthly cost during the three full months immediately preceding such termination of Consultant's reimbursed expenses set forth in Section 1.7;

(iii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by the Company's stock option plans or ten years following the Termination Date;

(iv) payment in respect of compensation earned but not yet paid (the "Compensation Payment") which amount shall be paid in a cash lump sum within ten (10) days of the date of termination; and

(v) payment of the cost of comprehensive medical insurance for Executive for the greater of the then remaining term of this Agreement or for a period of twelve months following the termination.

(b) For purposes of this Agreement, "Good Reason" shall mean any of the following (without Executive's express prior written consent):

(i) Any material breach by Company of any provision of this Agreement, including any material reduction by Company of Executive's duties or responsibilities (except in connection with the termination of Executive's employment for Cause, as a result of Permanent Disability, as a result of Executive's death or by Executive other than for Good Reason);

(ii) A reduction by the Company in Executive's Base Salary or any failure of the Company to reimburse

Executive for material expenses described in Section 1.7;

(iii) The failure by the Company to obtain the specific assumption of this Agreement by any successor or assign of Company as provided for in Section 8.6 hereof;

(iv) Moving the principal offices of Company to a location outside of the Metropolitan New York Area; or

(v) Upon a Change of Control of Company (as such term is hereinafter defined).

(c) The following provisions shall apply in the event compensation provided in Section 0 becomes payable to the Executive:

(i) if the severance compensation provided for in subsection 0 above cannot be finally determined on or before the tenth day following such termination, the Company shall pay to the Executive on such day an estimate, as determined in good faith by the Company of the minimum amount of such compensation and shall pay the remainder of such compensation (together with interest at the Federal short-term rate provided in Section 1274(d)(7)(C)(1) of the Code) as soon as the amount thereof can be determined but in no event later than the thirtieth day after the Date of Termination. In the event the amount of the estimated payment exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to the Executive payable on the fifth day after demand by the Company (together with interest at the Federal short-term rate provided in Section 1274(d)(7)(C)(1) of the Code).

(ii) If the payment of the Total Payments (as defined below) will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code, the Company shall pay the Executive on or before the tenth day following the Date of Termination, an additional amount (the "Gross-Up Payment") such that the net amount retained by the

Executive, after deduction of any Excise Tax on Total Payments and any federal and state and local income tax and Excise Tax upon the payment provided for by this paragraph, shall be equal to the Total Payments. For purposes of determining whether any of the payments will be subject to the Excise Tax and the amount of such Excise Tax, (A) any payments or benefits received or to be received by the Executive in connection with a Change in Control of the Company or the Executive's termination of employment, whether payable pursuant to the terms of Section 10 of this Agreement or any other plan, arrangement or agreement with the Company, its successors, any person whose actions result in a Change in Control of the Company or any corporation affiliated (or which, as a result of the completion of transaction causing such a Change in control, will become affiliated) with the Company within the meaning of Section 1504 of Code (the "Total Payments") shall be treated as "parachute payments" within the meaning of Section 28OG(b)(2) of the Code, and all "excess parachute payments" within the meaning of Section 28OG(b)(1) shall be treated as subject to the Excise Tax, unless, in the opinion of tax counsel selected by the Company's independent auditors and acceptable to the Executive, the Total Payments (in whole or in part) do not constitute parachute payments, or such excess parachute payments (in whole or in part) represent reasonable compensation for services actually rendered within the meaning of Section 28OG(b)(4) of the Code either in their entirety or in excess of the base amount within the meaning of Section 28OG(b)(3) of the Code, or are otherwise not subject to the Excise Tax, (B) the amount of the Total Payments that shall be treated as subject to the Excise Tax shall be equal to the lesser of (I) the total amount of the Total Payments or (II) the amount of excess parachute payments or benefit shall be determined by the Company's independent auditors in accordance with the principles of Section 28OG(d)(3) and (4) of the Code. For purposes of determining the amount of the Gross-Up Payment, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation in the calendar year in which the Gross-Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of the Executive's residence an the Date of Termination, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. In the event the Excise Tax is subsequently determined to be less than the amount taken into account hereunder at the time of termination of the Executive's employment, the Executive shall repay to the Company at the time the amount of such reduction in Excise Tax is finally determined the portion of the Gross-Up Payment that can be repaid such that

the Executive remains whole on an after-tax basis following such repayment (taking into account any reduction in income or excise taxes to the Executive from such repayment) plus interest on the amount of such repayment at the Federal short-term rate provided in Section 1274(d)(1)(C)(i) of the Code. In the event the Excise Tax is determined to exceed the amount taken into account hereunder at the time of the termination of the Executive's employment (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-Up Payment), the Company shall make an additional gross-up payment in respect of such excess (plus any interest payable with respect to such excess) at the time that the amount of such excess is finally determined.

4.2 Permanent Disability. If Executive becomes totally and permanently disabled (as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof) ("Permanent Disability"), Company or Executive may terminate this Agreement on written notice thereof, and Executive shall receive or commence receiving, as soon as practicable:

(a) amounts payable pursuant to the terms of the disability insurance policy or similar arrangement which Company maintains for the Executive, if any, during the term hereof;

(a) the Compensation Payment which shall be paid to Executive as a cash lump sum within 30 days of such termination; and

(b) immediate vesting of all unvested stock options.

4.3 Death. In the event of Executive's death during the term of his employment hereunder, Executive's estate or designated beneficiaries shall receive or commence receiving, as soon as practicable in accordance with the terms of this Agreement:

(a) compensation equal to one year's Base Salary (calculate by multiplying the average monthly Base Salary paid or accrued for the three full calendar months immediately such event, which shall be paid within 30 days of such termination;

(b) any death benefits provided under the Executive benefit programs, plans and practices in which the Executive has an interest, in accordance with their respective terms;

(c) the Compensation Payment which shall be paid to Executive's estate as a cash lump sum within 30 days of such termination; and

(c) such other payments under applicable plans or programs to which Executive's estate or designated beneficiaries are entitled pursuant to the terms of such plans or programs.

4.4 Voluntary Termination by Executive: Discharge for Cause. The Company shall have the right to terminate this Agreement for Cause (as hereinafter defined). In the event that Executive's employment is terminated by Company for Cause, as hereinafter defined, or by Executive other than for Good Reason or other than as a result of the Executive's Permanent Disability or death, prior to the Termination Date, Executive shall be entitled only to receive, as a cash lump sum within 30 days of such termination, the Compensation Payment. As used herein, the term "Cause" shall be limited to (a) willful malfeasance or willful misconduct by Executive in connection with the services to the Company in a matter of material importance to the conduct of the Company's affairs which has a material adverse affect on the business of the Company, or (b) the conviction of Executive for commission of a felony. For purposes of this subsection, no act or failure to act on the Executive's part shall be considered "willful" unless done, or omitted to be done, by the Executive not in good faith and without reasonable belief that his action or omission was in the best interest of the Company. Termination of this Agreement for Cause pursuant to this Section 0 shall be made by delivery to Executive of a copy of a resolution duly adopted by the affirmative vote of all of the members of the Board of Directors called and held for such purpose (after 30 days prior written notice to Executive and reasonable opportunity for Executive to be heard before the Board of Directors prior to such vote), finding that in the good faith business judgment of such Board of Directors, Executive was guilty of conduct set forth in any of clauses (a) through (b) above and specifying the particulars thereof.

5. Change In Control.

5.1 Definition. For purposes of this Agreement, a "Change in Control" shall be deemed to have occurred if (i) there shall be consummated (A) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation or pursuant to which shares of the Company's Common Stock would be converted into cash, securities or other property, other than a merger of the Company in which the holders of the Company's Common Stock immediately prior to the merger have substantially the same proportionate ownership of common stock of the surviving corporation immediately after the merger, or (B) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of the Company, or (ii) the stockholders of the Company shall approve any plan or proposal for the liquidation or dissolution of the Company, or (iii) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company or any executive benefit plan sponsored by the Company, or such person on the Effective Date hereof is a 20% or more beneficial owner, shall become the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company representing

20% or more of the combined voting power of the Company's then outstanding securities ordinarily (and apart from rights accruing in special circumstances) having the right to vote in the election of directors, as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, or (iv) at any time during a period of two consecutive years, individuals who at the beginning of such period, constituted the Board of Directors of the Company shall cease for any reason to constitute at least a majority thereof, unless the election or the nomination for election by the Company's stockholders of each new director during such two-year period was approved by a vote of at least two-thirds of the directors then still in office, who were directors at the beginning of such two-year period.

5.2 Rights and Obligations. If a Change in Control of the Company shall have occurred while the Executive is director of the Company, the Executive shall be entitled to the compensation provided in Section 0 of this Agreement upon the subsequent termination of this Agreement by either the Company, or the Executive within two years of the date upon which the Change in Control shall have occurred, unless such termination is a result of (i) the Executive's death; (ii) the Executive's Disability; (iii) the Executive's Retirement; or (iv) the Executive's termination for Cause.

6. Assignment**.** This Agreement shall be binding upon and inure to the benefit of the heirs and representatives of Executive and the assigns and successors of Company, but neither this Agreement nor any rights or obligations hereunder shall be assignable or otherwise subject to hypothecation by Executive (except by will or by operation of the laws of intestate succession or by Executive notifying the Company that cash payment be made to an affiliated investment partnership in which Executive is a control person) or by Company, except that Company may assign this Agreement to any successor (whether by merger, purchase or otherwise) to all or substantially all of the stock, assets or businesses of Company, if such successor expressly agrees to assume the obligations of Company hereunder.

7. Indemnification**.**

Executive, as such and as a Director of the Company, shall be indemnified by the Company against all liability incurred by the Executive in connection with any proceeding, including, but not necessarily limited to, the amount of any judgment obtained against Executive, the amount of any settlement entered into by the Executive and any claimant with the approval of the Company, attorneys' fees, actually and necessarily incurred by him in connection with the defense of any action, suit, investigation or proceeding or similar legal activity, regardless of whether criminal, civil, administrative or investigative in nature ("Claim"), to which he is made a party or is otherwise subject to, by reason of his being or having been a director, officer, agent or employee of the Company, to the full extent permitted by applicable law and the Certificate of Incorporation of the Company.. Such right of indemnification will not be deemed exclusive of any other rights to which Executive may be entitled under Company's Certificate of Incorporation or By-laws, as in effect from time to time, any agreement or otherwise.

8. General Provisions.

8.1 Modification: No Waiver. No modification, amendment or discharge of this Agreement shall be valid unless the same is in writing and signed by all parties hereto. Failure of any party at any time to enforce any provisions of this Agreement or any rights or to exercise any elections hall in no way be considered to be a waiver of such provisions, rights or elections and shall in no way affect the validity of this Agreement. The exercise by any party of any of its rights or any of this elections under this Agreement shall not preclude or prejudice such party from exercising the same or any other right it may have under this Agreement irrespective of any previous action taken.

8.2 Notices. All notices and other communications required or permitted hereunder or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when hand delivered or mailed by registered or certified mail as follows (provided that notice of change of address shall be deemed given only when received):

If to the Company, to:

Synergy Pharmaceuticals Inc.
420 Lexington Avenue, Suite 60
New York, NY 10070

If to Executive, to:
Gary S. Jacob, Ph.D.
171 East 84th Street, #16J
New York, NY 10028

Or to such other names or addresses as the Company or Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section.

8.3 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

8.4 Further Assurances. Each party to this Agreement shall execute all instruments and documents and take all actions as may be reasonably required to effectuate this Agreement.

8.5 Severability. Should any one or more of the provisions of this Agreement or of any agreement entered into pursuant to this Agreement be determined to be illegal or unenforceable, then such illegal or unenforceable provision shall be modified by the proper court or arbitrator to the extent necessary and possible to make such provision enforceable, and such modified provision and all other provisions of this Agreement and of each other agreement entered into pursuant to this Agreement shall be given effect separately from the provisions or portion thereof determined to be illegal or unenforceable and shall not be affected thereby.

8.6 Successors and Assigns. Executive may not assign this Agreement without the prior written consent of the Company. The Company may assign its rights without the written consent of the executive, so long as the Company or its assignee complies with the other material terms of this Agreement. The rights and obligations of the Company under this Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company, and the Executive's rights under this Agreement shall inure to the benefit of and be binding upon his heirs and executors. The Company's subsidiaries and controlled affiliates shall be express third party beneficiaries of this Agreement.

8.7 Entire Agreement. This Agreement supersedes all prior agreements and understandings between the parties, oral or written. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

8.8 Counterparts; Facsimile. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original, and all of which taken together shall constitute one and the same instrument. This Agreement may be executed by facsimile with original signatures to follow.

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, have executed this Agreement as of the date first written above.

EXECUTIVE:	SYNERGY PHARMACEUTICALS INC.
/s/ Gary S. Jacob	/s/ Bernard Denoyer
Gary S. Jacob, Ph.D.	Bernard Denoyer, Senior Vice President, Finance

Exhibit 10.4

CONSULTING AGREEMENT

This CONSULTING AGREEMENT (the "Agreement") is made and entered into as of the 28th day of December 2012 by and between Gabriele M. Cerrone ("Consultant") and Synergy Pharmaceuticals Inc., a Delaware corporation (the "Company").

WHEREAS, the Company desires to engage Consultant to provide certain consulting services, and Consultant is willing to be engaged by the Company to provide such services, on the terms and conditions set forth below;

WHEREAS, the Company understands that the Consultant will be performing substantially all of his consulting services pursuant to this Agreement outside of the U.S;

WHEREAS, the Consultant has previously entered into a consulting agreement with the Company as of March 11, 2009, as amended by the Amended and Restated Consulting Agreement entered into with the Company as of February 10, 2010 and the Second Amended and Restated Employment Agreement with the Company as of May 2, 2011(the "Prior Consulting Agreement"); and

WHEREAS, the parties wish to enter into a new Agreement between the Consultant and the Company in its entirety, on the terms and conditions contained in this Agreement, which will supersede the Prior Consulting Agreement and all prior agreements and understandings between the parties, oral or written.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Purpose**: The Company hereby engages Consultant for the term specified in Paragraph 2 hereof to render consulting advice to the Company relating to business development, corporate finance and capital markets matters upon the terms and conditions set forth herein.

2. **Effective Date and Term:**

2.1 Effective Date. This Agreement became effective as of January 1, 2013 (the "Effective Date").

2.2 Term. Unless earlier terminated pursuant to Section 10 hereof, the term of this Agreement shall commence on the Effective Date and shall continue from the Effective Date to December 31, 2016 (the "Initial Term"). This Agreement shall thereafter be automatically renewed for successive one year periods (each a "Renewal Term") unless either party shall notify the other in writing of its intention not to renew this Agreement (a "Non-renewal Notice"), which notice shall be given at least 60 days prior to the end of the then current term (the "Expiration Date"). The period from the

Effective Date to the Expiration Date, including the Renewal Terms, if any, is referred to herein as the "Term."

3. **Duties of Consultant:** During the term of this Agreement, the Consultant shall devote such portion of his business time and attention to affairs of the Company reasonably necessary to provide the Company with such regular and customary business development, strategic planning, capital markets and corporate finance consulting advice as is reasonably requested by the Company's management and Board of Directors, provided that Consultant shall not be required to undertake duties not reasonably within the scope of this Agreement. So long as the Consultant serves as a member of the Company's Board of Directors, Consultant shall serve as Chairman of the Board; provided, at the request of all of the members of the Board of Directors (not counting the Consultant), the Consultant will relinquish his title as Chairman to the Company's duly appointed chief executive officer, and accept the title of Vice Chairman.

3.1. Permissible Services. The Consultant's services will include advising the Company's Board of Directors and senior management on the following matters:

(i) in-licensing and out-licensing technologies and compounds;
(ii) capitalization and corporate organization of the Company;
(iii) structure and pricing of offerings of the Company's securities in public and private transactions;
(iv) alternative uses of corporate assets;
(v) structure and use of debt;
(vi) application and maintenance of listing of the Company's stock in securities exchanges and other appropriate markets;
(vii) strategic planning
(viii) management recruitment and compensation; and
(ix) presentations to institutional and professional individual investors in Europe, Asia and the U.S.

3.2 Prohibited Services. The services to be rendered by the Consultant to the Company shall not (unless the Consultant is appropriately licensed, registered or there is an exemption available from such licensing or registration) include, directly or indirectly: any activities which require the Consultant to register as a broker-dealer under the Securities Exchange Act of 1934, as amended.

4. **<u>Consulting Fee:</u>** :

4.1. <u>Base Consulting Fee</u>. In consideration for the services rendered by Consultant to the Company pursuant to this Agreement, the Company agrees to pay Consultant the annual sum of $425,000 at the rate of $35,416.67 per month commencing on the Effective Date ("Base Consulting Fee"). The Consultant's Base Consulting Fee may be increased, but not decreased by the Board or the Compensation Committee of the Board (the "Compensation Committee"). Once increased, such increased amount shall constitute the Consultant's Base Consulting Fee and shall not be decreased. The Company will include the shares of equity securities of the Company which may be issued upon the exercise of the options held by Consultant in any registration statement under the Securities Act of 1933 which includes securities issuable to any other executive officer of the Company.

4.2. <u>Incentive Payments.</u>

(a) Annual <u>Bonus</u>. Consultant shall be eligible to earn a cash bonus of up to 50% of his Base Consulting Fee per full calendar year during the Term based on meeting performance objectives and bonus criteria to be mutually identified by Consultant and the Compensation Committee. The bonus shall be determined on or before March 1 of each year of the Employment Term commencing January 1, 2013 and paid on or before April 14 of each year.

(b) <u>Realization Bonus</u>.

(i) In the event during the Term of this Agreement the Company enters into either a out-license agreement for any of its technology that grants exclusive marketing rights to a third party (and the license fees the Company contracts to receive (disregarding any contingencies to such payment) equals or exceeds $50 million) or enters into a joint venture in which the Company contributes such rights to the joint venture, in each case where the Enterprise Value (defined below) equals or exceeds the minimum value of $250 million, the Consultant shall accrue a bonus in an amount determined by multiplying the Enterprise Value (defined below) in the case of a joint venture or the sum of the license fees actually received, in the case of an out-license, as the case may be, by 0.5% (one half percent).

(ii) In the event during the Term of this Agreement the Company:

(A) engages in (i) a merger transaction, as a result of which the stockholders of the Company existing immediately before the consummation of such merger own beneficially less than 20% of the stock of the ultimate parent of the surviving entity immediately after the consummation of the merger where the Enterprise Value equals or exceeds a minimum value of $400 million or (ii) a sale of substantially all of the assets of the Company where the Enterprise Value equals or exceeds a minimum value of $400 million, the Consultant shall accrue a bonus in an amount determined by multiplying the Enterprise Value by 2.5% (a "Sale Transaction"); or

(B) engages in (i) a merger transaction, as a result of which the stockholders of the Company existing immediately before the consummation of such merger own beneficially 20% or more of the stock of the ultimate parent of the surviving entity immediately after the consummation of the merger where the Enterprise Value of the Company either at the effective date of the transaction or 12 months after the effective date of the transaction) equals or exceeds a minimum value of $250 million or (ii) a sale of substantially all of the assets of the Company where the Enterprise Value equals or exceeds a minimum value of $250 million, the Consultant shall accrue a bonus in an amount determined by multiplying the Enterprise Value by 2.5% (a "Combination Transaction").

(iii) The accrued bonuses shall be payable to Consultant: (a) in the same form of the consideration received by the Company's stockholders in full contemporaneously at the closing of any joint venture, Sale Transaction or Combination Transaction; or (b) in cash 5 full business days after the Company's receipt of license fees at the rate of 0.5% of license fees actually received. The expiration or termination of this Agreement shall not terminate or diminish the Consultant's right to receive bonus payments with respect to out license fees collected or the consummation of any joint venture, Sale Transaction or Combination Transaction after the termination or expiration of this Agreement provided the Company has entered into an agreement for such a transaction any time during the Term or 90 days thereafter.

(iv) The "Enterprise Value" in the case of a Change in Control in which consideration is payable to the Company in respect of its assets or business, shall mean the total cash and non-cash (including, without limitation, the assumption of debt) consideration received by the Company or in the case of a Change in Control in which consideration is payable to the Company's stockholders, the total cash and non-cash (including, without limitation, the assumption of debt) consideration payable to the Company's stockholders. "Enterprise Value" shall also include, if applicable, any cash or non-cash consideration payable to the

Company or to the Company's stockholders on a contingent, earnout or deferred basis. To the extent that any consideration in a transaction is not received in cash upon the consummation of the Change in Control, the value of such non-cash consideration for purposes of calculating the Enterprise Value will be determined by the independent Board of Directors of the Company prior to the Change in Control in good faith in consultation with an independent investment bank or financial advisor retained by Board of Directors in connection with the Change in Control transaction. In the event that less than 100% of the stock or assets of the Company is purchased in the Change in Control transaction, the Enterprise Value shall be extrapolated from the percentage of the Company's capital stock or assets impacted in such Change in Control transaction to determine if the applicable threshold was exceeded, but the Transaction Fee shall be calculated based on the actual consideration received by the Company or shareholders, as the case may be. Section 4.2(b), however, shall not apply to any event resulting in a Change in Control in which neither the Company nor its stockholders receives consideration either upon, or in connection with, the occurrence or consummation of the event resulting in a Change in Control.

(v) For purposes of Section 4.2(b)(ii)(B), Enterprise Value at any time subsequent to the effective date of a transaction shall be computed by reference to the market capitalization of the combined entity (based on an average closing price of the combined entities common stock for a period of 20 consecutive trading days) multiplied by the quotient of the number of combined entities shares of common stock and common stock equivalents issued to the Company's stockholders in the transaction divided by the total number of shares of the common stock and common stock equivalents outstanding on the effective date of the transaction, on a fully diluted basis.

(c) Options. The Compensation Committee will consider grants of options to the Consultant no less frequently than annually commencing January 1, 2013.

5. **Expenses and Services:**

5.1 Consultant is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement, including, without limitation, expenses for travel (at the fare class no less favorable than that of other executive officers of the Company), cellular telephone (including access charges and business calls), electronic market data services consisting of a full office-based and portable Bloomberg information services, the cost associated with accessing office facilities and administrative assistance outside of the Company's principal executive offices at such times that the

Consultant is attending to matters within the scope of this Agreement and business entertainment. Additionally, the Consultant is authorized to incur reasonable expenses for the attendance of conferences in fields relate to technology of interest to the Company, finance of biotechnology ventures, and similar events related to Consultant's duties and responsibilities as Consultant deems necessary. Company will reimburse Consultant for all such expenses upon presentation by Consultant of appropriately itemized accounts of such expenditures or the Company will pay such expenses directly.

5.2 During the Term, the Company will at its sole expense provide the Consultant with computing hardware and software tools, office facilities and qualified, access to Company information and financial records and an experienced administrative assistant and such legal and accounting support services as is deemed appropriate by the Consultant. Such services and facilities will not be diminished without the Consultant's prior consent.

5.3 In the event this Agreement is terminated other than for Cause or voluntarily by the Consultant, the Company, in addition to any other termination benefit, will make a lump sum payment to Consultant equal to the higher of the aggregate amount of the sum of average monthly cost during the three full months immediately preceding such termination of providing the services to Consultant set forth in Section 5.1 and Consultant's reimbursed expenses set forth in Section 5.2 for the then remaining term of this Agreement or twelve times the sum of average monthly cost during the three full months immediately preceding such termination of providing the services to Consultant set forth in Section 5.1 and Consultant's reimbursed expenses set forth in Section 5.2. Such lump sum payments shall be made no later than 30 days after termination. In the event of a disagreement between the Company as to the amount of such lump sum payment, the Company shall pay the amount as to which there is no dispute, pending the settlement of any amounts as to which there is a dispute.

6. **Liability of Consultant:** The Company acknowledges that all opinions and advice (written or oral) given by Consultant to the Company in connection with Consultant's engagement are intended solely for the benefit and use of the Company in considering the transaction to which they relate, and the Company agrees that no person or entity other than the Company shall be entitled to make use of or rely upon the advice of Consultant to be given hereunder, and no such opinion or advice shall be used for any other purpose or reproduced, disseminated, quoted or referred to at any time, in any manner or for any purpose, nor may the Company make any public references to Consultant, or use

Consultant's name in any annual reports or any other reports or releases of the Company without Consultant's prior written consent. Consultant's maximum liability shall not exceed the cash payments received from the Company.

7. **Consultant's Services to Others:** The Company acknowledges that Consultant and its affiliates are in the business of investing and providing financial services and consulting advice to others. Nothing herein contained shall be construed to limit or restrict

Consultant in conducting such business with respect to others, or in rendering such advice to others.

8. **Company Information:**

a. The Company recognizes and confirms that, in advising the Company and in fulfilling his engagement hereunder, Consultant will use and rely on data, material and other information furnished to Consultant by the Company. The Company acknowledges and agrees that in performing his services under this engagement, Consultant may rely upon the data, material and other information supplied by the Company without independently verifying the accuracy, completeness or veracity of same. The Company agrees to notify Consultant in writing via overnight courier, facsimile or e-mail of any material event and/or change with in twenty-four hours of its occurrence.

b. Consultant recognizes and acknowledges that by reason of Consultant's retention by and service to the Company before, during and, if applicable, after the Term, Consultant will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales techniques, strategy and programs, computer programs and software and financial information relating to the field of in which the Company is actually engaged in research, development, collaboration or sales at the time of such disclosure (collectively referred to as "Confidential Information"). Consultant acknowledges that such Confidential Information is a valuable and unique asset of the Company and Consultant covenants that it will not, unless expressly authorized in writing by the Company, at any time during the Consulting Term use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Consultant's duties for the Company and in a manner consistent with the Company's policies regarding Confidential Information. Consultant also covenants that at any time after the termination of this Agreement, directly or indirectly, it will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Consultant or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee

thereof) with apparent jurisdiction to order Consultant to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Consultant's possession during the Consulting Term shall remain the property of the Company. Except as required in the performance of Consultant's duties for the Company, or unless expressly authorized in writing by the Company, Consultant shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Consultant's duties for the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of this Agreement, the Consultant agrees to return immediately to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Consultant's possession. .

9. **Consultant an Independent Contractor:** Consultant shall perform its services hereunder as an independent contractor and not as an employee of the Company or an affiliate thereof. It is expressly understood and agreed to by the parties hereto that Consultant shall have no authority to act for, represent or bind the Company or any affiliate thereof in any manner, except as may be agreed to expressly by the Company in writing from time to time.

10. **Termination:**

10.1 Termination Without Cause or for Good Reason.

(a) If this Agreement is terminated by the Company other than for Cause (as defined in Section 10.4 hereof) or as a result of Consultant's death or Permanent Disability (as defined in Section 10.2 hereof), or if Consultant terminates his engagement for Good Reason (as defined in Section 10.1 (b) hereof) prior to the Expiration Date, Consultant shall receive or commence receiving as soon as practicable in accordance with the terms of this Agreement:

(i) a severance payment (the "Severance Payment"), which amount shall be paid in a cash lump sum within ten (10) days of the date of termination, in an amount equal to the higher of the aggregate amount of the Consultant's Base Consulting Fee for the then remaining term of this Agreement or twelve times the average monthly Base Consulting Fee paid or accrued during the three full months immediately preceding such termination;

(ii) expense compensation, which shall be paid in a lump sum payment within ten (10) days of the date of termination, in an amount equal to the higher of the aggregate amount of the sum of average monthly cost during the three full

months immediately preceding such termination of providing the services to Consultant set forth in Section 5.1 and Consultant's reimbursed expenses set forth in Section 5.2 for the then remaining term of this Agreement or twelve times the sum of average monthly cost during the three full months immediately preceding such termination of providing the services to Consultant set forth in Section 5.1 and Consultant's reimbursed expenses set forth in Section 5.2;

(ii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by the Company's stock option plans or ten years following the Termination Date;

(iii) payment in respect of consulting fees and bonus earned but not yet paid (the "Consulting Payment") which amount shall be paid in a cash lump sum within ten (10) days of the date of termination; and

(iv) payment of the cost of comprehensive medical insurance for Consultant for the greater of the then remaining term of this Agreement or for a period of twelve months following the termination.

(b) For purposes of this Agreement, "Good Reason" shall mean any of the following (without Consultant's express prior written consent):

(i) Any material breach by Company of any provision of this Agreement, including any material reduction by Company of Consultant's duties or responsibilities (except in connection with the termination of Consultant's employment for Cause, as a result of Permanent Disability, as a result of Consultant's death or by Consultant other than for Good Reason);

(ii) A reduction by the Company in Consultant's Base Consulting Fee or any failure of the Company to reimburse Consultant for material expenses described in Section 5.1 or provide the services described in Section 5.2 of this Agreement;

(iii) The failure by the Company to obtain the specific assumption of this Agreement by any successor or assign of Company as provided for in Section 11 hereof; or

(iv) Upon a Change of Control of Company (as such term is hereinafter defined).

(c) The following provisions shall apply in the event the payments provided in Section 10.1 (a) becomes payable to the Consultant:

(i) In the event the severance payments provided for in subsection 10.1(a) above cannot be finally determined on or before the tenth day following such termination, the Company shall pay to the Consultant on such day an estimate, as determined in good faith by the Company of the minimum amount of such payments and shall pay the remainder of such amount (together with interest at the Federal short-term rate provided in Section 1274(d)(7)(C)(1) of the Code) as soon as the amount thereof can be determined but in no event later than the thirtieth day after the Date of Termination. In the event the amount of the estimated payment exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to the Consultant payable on the fifth day after demand by the Company (together with interest at the Federal short-term rate provided in Section 1274(d)(7)(C)(1) of the Code).

(ii) If the payment of the Total Payments (as defined below) will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code, the Company shall pay the Consultant on or before the tenth day following the Date of Termination, an additional amount (the "Gross-Up Payment") such that the net amount retained by the Consultant, after deduction of any Excise Tax on Total Payments and any federal and state and local income tax and Excise Tax upon the payment provided for by this paragraph, shall be equal to the Total Payments. For purposes of determining whether any of the payments will be subject to the Excise Tax and the amount of such Excise Tax, (A) any payments or benefits received or to be received by the Consultant in connection with a Change in Control of the Company or the Consultant's termination of employment, whether payable pursuant to the terms of Section 10 of this Agreement or any other plan, arrangement or agreement with the Company, its successors, any person whose actions result in a Change in Control of the Company or any corporation affiliated (or

which, as a result of the completion of transaction causing such a Change in control, will become affiliated) with the Company within the meaning of Section 1504 of Code (the "Total Payments") shall be treated as "parachute payments" within the meaning of Section 28OG(b)(2) of the Code, and all "excess parachute payments" within the meaning of Section 28OG(b)(1) shall be treated as subject to the Excise Tax, unless, in the opinion of tax counsel selected by the Company's independent auditors and acceptable to the Consultant, the Total Payments (in whole or in part) do not constitute parachute payments, or such excess parachute payments (in whole or in part) represent reasonable compensation for services actually rendered within the meaning of Section 28OG(b)(4) of the Code either in their entirety or in excess of the base amount within the meaning of Section 28OG(b)(3) of the Code, or are otherwise not subject to the Excise Tax, (B) the amount of the Total Payments that shall be treated as subject to the Excise Tax shall be equal to the lesser of (I) the total amount of the Total Payments or (II) the amount of excess parachute payments or benefit shall be determined by the Company's independent auditors in accordance with the principles of Section 28OG(d)(3) and (4) of the Code. For purposes of determining the amount of the Gross-Up Payment, the Consultant shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation in the calendar year in which the Gross-Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of the Consultant's residence an the Date of Termination, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. In the event the Excise Tax is subsequently determined to be less than the amount taken into account hereunder at the time of termination of the Consultant's employment, the Consultant shall repay to the Company at the time the amount of such reduction in Excise Tax is finally determined the portion of the Gross-Up Payment that can be repaid such that the Consultant remains whole on an after-tax basis following such repayment (taking into account any reduction in income or excise taxes to the Consultant from such repayment) plus interest on the amount of such repayment at the Federal short-term rate provided in Section 1274(d)(1)(C)(i) of the Code. In the event the Excise Tax is determined to exceed the amount taken into account hereunder at the time of the termination

of the Consultant's employment (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-Up Payment), the Company shall make an additional gross-up payment in respect of such excess (plus any interest payable with respect to such excess) at the time that the amount of such excess is finally determined.

10.2 Permanent Disability. If Consultant becomes totally and permanently disabled (as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof) ("Permanent Disability"), Company or Consultant may terminate this Agreement on written notice thereof, and Consultant shall receive or commence receiving, as soon as practicable:

(i) amounts payable pursuant to the terms of the disability insurance policy or similar arrangement which Company maintains for the Consultant, if any, during the term hereof;

(ii) the Consulting Payment which shall be paid to Consultant as a cash lump sum within 30 days of such termination; and

(iii) immediate vesting of all unvested stock options.

10.3 Death. In the event of Consultant's death during the term of his employment hereunder, Consultant's estate or designated beneficiaries shall receive or commence receiving, as soon as practicable in accordance with the terms of this Agreement:

(i) a payment equal to one year's Base Consulting Fee which shall be paid within 30 days of such termination;

(ii) any death benefits provided under the Consultant benefit programs, plans and practices in which the Consultant has an interest, in accordance with their respective terms;

(iii) the Consulting Payment which shall be paid to Consultant's estate as a cash lump sum within 30 days of such termination; and

(iv) such other payments under applicable plans or programs to which Consultant's estate or designated beneficiaries are entitled pursuant to the terms of such plans or programs.

10.4 Voluntary Termination by Consultant: Discharge for Cause. The Company shall have the right to terminate this Agreement for Cause (as hereinafter defined). In the event that Consultant's employment is terminated by Company for Cause, as hereinafter defined, or by Consultant other than for Good Reason or other than as a result of the Consultant's Permanent Disability or death, prior to the Termination Date, Consultant shall be entitled only to receive, as a cash lump sum within 30 days of such termination, the Consulting Payment. As used herein, the term "Cause" shall be limited to (i) willful malfeasance or willful misconduct by Consultant in connection with the services to the Company in a matter of material importance to the conduct of the Company's affairs which has a material adverse affect on the business of the Company, or (ii) the conviction of Consultant for commission of a felony. For purposes of this subsection, no act or failure to act on the Consultant's part shall be considered "willful" unless done, or omitted to be done, by the Consultant not in good faith and without reasonable belief that his action or omission was in the best interest of the Company. Termination of this Agreement pursuant to this Section 10.4 shall be made by delivery to Consultant of a copy of a resolution duly adopted by the affirmative vote of all of the members of the Board of Directors called and held for such purpose (after 30 days prior written notice to Consultant and reasonable opportunity for Consultant to be heard before the Board of Directors prior to such vote), finding that in the good faith business judgment of such Board of Directors, Consultant was guilty of conduct set forth in any of clauses (i) through (ii) above and specifying the particulars thereof.

11. Assignment:

This Agreement shall be binding upon and inure to the benefit of the heirs and representatives of Consultant and the assigns and successors of Company, but neither this Agreement nor any rights or obligations hereunder shall be assignable or otherwise subject to hypothecation by Consultant (except by will or by operation of the laws of intestate succession or by Consultant notifying the Company that cash payment be made to an affiliated investment partnership in which Consultant is a control person) or by Company, except that Company may assign this Agreement to any successor (whether by merger, purchase or otherwise) to all or substantially all of the stock, assets or businesses of Company, if such successor expressly agrees to assume the obligations of Company hereunder.

12. Change In Control:

12.1 Definition. For purposes of this Agreement, a "Change in Control" shall be deemed to have occurred if (i) there shall be consummated (A) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation or pursuant to which shares of the Company's Common Stock would be converted into cash, securities or other property, other than a merger of the Company in which the holders of the Company's Common Stock immediately prior to the merger have substantially the same proportionate

ownership of common stock of the surviving corporation immediately after the merger, or (B) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all the assets of the Company, or (ii) the stockholders of the Company shall approve any plan or proposal for the liquidation or dissolution of the Company, or (iii) any person (as such term is used in Sections 13(d) and 14(d)(2) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company or any Consultant benefit plan sponsored by the Company, or such person on the Effective Date hereof is a 20% or more beneficial owner, shall become the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company representing 20% or more of the combined voting power of the Company's then outstanding securities ordinarily (and apart from rights accruing in special circumstances) having the right to vote in the election of directors, as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, or (iv) at any time during a period of two consecutive years, individuals who at the beginning of such period, constituted the Board of Directors of the Company shall cease for any reason to constitute at least a majority thereof, unless the election or the nomination for election by the Company's stockholders of each new director during such two-year period was approved by a vote of at least two-thirds of the directors then still in office, who were directors at the beginning of such two-year period.

12.2 Rights and Obligations. If a Change in Control of the Company shall have occurred while the Consultant is director of the Company, the Consultant shall be entitled to the payments provided in Section 10.1 of this Agreement upon the subsequent termination of this Agreement by either the Company, or the Consultant within two years of the date upon which the Change in Control shall have occurred, unless such termination is a result of (i) the Consultant's death; (ii) the Consultant's Disability; (iii) the Consultant's Retirement; or (iv) the Consultant's termination for Cause.

7. Indemnification:

Consultant, as such and as a Director of the Company, shall be indemnified by the Company against all liability incurred by the Consultant in connection with any proceeding, including, but not necessarily limited to, the amount of any judgment obtained against Consultant, the amount of any settlement entered into by the Consultant and any claimant with the approval of the Company, attorneys' fees, actually and necessarily incurred by him in connection with the defense of any action, suit, investigation or proceeding or similar legal activity, regardless of whether criminal, civil, administrative or investigative in nature ("Claim"), to which he is made a party or is otherwise subject to, by reason of his being or having been a director, officer, agent or employee of the Company, to the full extent permitted by applicable law and the Certificate of Incorporation of the Company. Such right of indemnification will not be deemed exclusive of any other rights to which Consultant may be entitled

under Company's Certificate of Incorporation or By-laws, as in effect from time to time, any agreement or otherwise.

14. **Miscellaneous:**

(a) This Agreement between the Company and Consultant constitutes the entire agreement and understanding of the parties hereto, and supersedes any and all previous agreements and understandings, whether oral or written, between the parties with respect to the matters set forth herein.

(b) Any notice or communication permitted or required hereunder shall be in writing and shall be deemed sufficiently given if hand-delivered or sent (i) postage prepaid by registered mail, return receipt requested, or (ii) by facsimile, to the respective parties as set forth below, or to such other address as either party may notify the other in writing.

If to the Company, to: Synergy Pharmaceuticals, Inc.
420 Lexington Avenue, Suite 1609
New York, New York 10170
Attention: Gary S. Jacob, CEO

If to Consultant, to: Gabriele M. Cerrone
Via Sant'Andrea 18
Milano Italy 20121

(c) This Agreement may be executed in any number of counterparts, each of whom together shall constitute one and the same original document.

(d) This Agreement may not be changed orally, but only by an agreement in writing signed by the party against whom any waiver, change, amendment, modification or discharge is sought.

(e) The invalidity of all or any part of any provision of this Agreement shall not render invalid the remainder of this Agreement or the remainder of such provision. If any provision of this Agreement is so broad as to be unenforceable, such provision shall be interpreted to be only so broad as is enforceable.

(f) This Agreement shall be governed by and construed in accordance with the law of the State of New York without giving effect to the principles of conflicts of law thereof. The parties hereto each hereby submits herself or itself for the sole purpose of this Agreement and any controversy arising hereunder to the exclusive jurisdiction of the state courts in the State of New York.

(g) Any amounts due hereunder to Consultant which remain unpaid after their due date, shall bear interest from the due date until paid at a rate of the prime rate (in effect on the date thereof for Citibank).

(h) The Company's obligations to make payments under Section 10 and 12 shall survive termination or expiration of this Agreement.

(i) Consultant shall not be required to mitigate damages or the amount of any payment provided for under this Agreement by seeking other employment or otherwise after the termination of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed, as of the date first above written.

CONSULTANT

/s/ Gabriele M. Cerrone
Gabriele M. Cerrone

SYNERGY PHARMACEUTICALS INC.

By: /s/ Gary S. Jacob
Name: Gary S. Jacob
Title: President and CEO

Exhibit 10.7

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

ASSET PURCHASE AGREEMENT

between

BRISTOL-MYERS SQUIBB COMPANY,

and

SYNERGY PHARMACEUTICALS, INC.

Dated as of August 17, 2012

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

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ASSET PURCHASE AGREEMENT dated as of August 17, 2012, between BRISTOL-MYERS SQUIBB COMPANY, a Delaware corporation ("Seller"), and SYNERGY PHARMACEUTICALS, INC., a Delaware corporation ("Purchaser").

Seller desires to sell, and Purchaser desires to purchase, that certain business of Seller and the Selling Affiliates as conducted on the date hereof consisting of the research, development, product design and related activities of Seller and the Selling Affiliates to the extent related solely to the Product (the "Business").

Certain capitalized terms used in this Agreement are defined in Section 11.07(b). Section 11.07(c) identifies other Sections of this Agreement in which capitalized terms used in this Agreement are defined.

Accordingly, the parties hereby agree as follows:

ARTICLE I

Purchase and Sale of Acquired Assets

SECTION 1.01. Purchase and Sale. (a) Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Seller shall, and shall cause the Selling Affiliates to, sell, assign, transfer, convey and deliver to Purchaser, and Purchaser shall purchase from Seller and the Selling Affiliates all the right, title and interest of . Seller and the Selling Affiliates in, to and under the Acquired Assets, for (a) a purchase price (the "Purchase Price") equal to the aggregate amount of (i) One Million Dollars ($1,000,000.00) (the "Base Purchase Price"), payable as set forth in Article II, (ii) the Milestone Consideration, payable in accordance with Section 1.02 and (iii) the Royalty Payments, payable in accordance with Sections 1.03 and 1.04, and (b) the assumption by Purchaser of the Assumed Liabilities. The purchase and sale of the Acquired Assets and the assumption by Purchaser of the Assumed Liabilities are referred to in this Agreement collectively as the "Acquisition".

(b) Within three (3) business days following receipt by Purchaser from Seller or the Selling Affiliates of the FV-100 active pharmaceutical ingredient and the related invoice, Purchaser shall pay to Seller by wire transfer to the bank account designated in writing by Seller pursuant to Section 2.01(b)(i) in United States Dollars immediately available funds the lesser of (i) amount of such invoice and (ii) Four Hundred Thousand Dollars ($400,000.00).

SECTION 1.02. Milestone Consideration.

(a) Milestones. Within five (5) business days after the occurrence of each of the milestone events set forth in the table in this Section 1.02(a) (each a "Milestone Event" and collectively the "Milestone Events") with respect to FV-100 (the valyl ester pro-drug of Cfl743, a bicyclic nucleoside analogue) (the "Product"), Purchaser shall pay to Seller by wire transfer of immediately available funds the applicable milestone amount set forth opposite each such Milestone Event (each milestone amount with respect to any Milestone Event being hereinafter referred to as a "Milestone Payment"). The milestone amounts are as follows:

Milestone Event	**Milestone Fee**
Marketing Approval	$ [*]
Upon aggregate Net Sales of the Product being equal to or greater than $125 million	$ [*]

[*] Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portion.

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In no event shall any Milestone Payment be refundable or returnable, or shall it be creditable against any Royalty Payments or any other payments which are or become due and payable by Purchaser to Seller under this Agreement or any of the Other Transaction Documents.

For the avoidance of doubt, in accordance with the foregoing, the maximum total Milestone Payments payable by Purchaser to Seller under this Section 1.02 would be [*] ($[*]).

(b) Achievement of Milestones. From and after the Closing Date and until the earliest of (i) payment, in full, by Purchaser of all Milestone Payments as required by this Agreement, (ii) Purchaser's determination using commercially reasonable standards consistent with the exercise of prudent scientific and business judgment and consistent with those standards used by Purchaser for its other therapeutic products at a similar stage of development and with similar commercial potential, to terminate the development of the Product before the corresponding Milestone Event has occurred, in which event Purchaser shall provide notice to Seller within fifteen (15) days after any such determination, and (iii) the tenth (10th) anniversary of the Closing Date, Purchaser shall use its commercially reasonable and diligent efforts (as defined in Section 11.07(b)) to achieve each of the Milestone Events.

(c) Access to Information. Within fifteen (15) days after the end of each six (6) month period following the Closing Date, and ending, with respect to any Milestone Event, on the earliest of (i) the date upon which the applicable Milestone Payment has been made, (ii) termination of the development or marketing program relating to such Milestone Event in compliance with Section 1.02(b)(ii), and (iii) except as provided in the parenthetical at the end of this sentence, the tenth (10th) anniversary of the Closing Date, Purchaser shall with respect to the Product furnish Seller with a reasonably detailed written report of its activity and progress toward achievement of the Milestone Events during the previous six month period (it being understood that in the event the reporting obligation under this subsection (c) terminates pursuant to clause (iii)" of this sentence, the report for the final six months of the ten year period following the Closing Date shall be provided within fifteen (15) days after the tenth (10th) anniversary of the Closing Date). Purchaser shall keep data and records concerning the activity and progress related to the Product, including, as applicable, the research and development activities, preclinical studies, clinical trials and regulatory filings and approvals related thereto in reasonably sufficient detail to verify Purchaser's compliance with this Section 1.02. Subject to confidentiality arrangements reasonably satisfactory to Purchaser and reasonable notice, Seller shall have the right to inspect, during normal business hours, such data and records not more than four (4) times in any twelve (12) calendar month period insofar as they relate to Purchaser's compliance with this Section 1.02 or the achievement of the Milestone Events.

(d) Disputes. Purchaser and Seller shall attempt in good faith to resolve any dispute as to whether a Milestone Event has occurred. If the parties do not reach agreement with respect to any such dispute within thirty (30) days after notice is given by Seller to Purchaser of its belief that a Milestone Event has occurred, the matter shall be referred for arbitration to a disinterested individual who has appropriate scientific, technical and regulatory expertise (as relevant) to resolve any disputes referred to him or her under this Agreement (a "Scientific Expert") who is mutually agreed to by Purchaser and Seller; *provided* that such Scientific Expert shall not be or have been at any time within the previous five (5) years an Affiliate, employee, consultant, officer or director of Purchaser or Seller or any of their respective Affiliates. If Purchaser and Seller cannot agree on a mutually acceptable Scientific Expert within thirty (30) calendar days after either party has determined that the parties cannot reach agreement with respect to a dispute, then within five (5) Business Days after the expiration of such thirty calendar day period, each of Purchaser and Seller shall appoint one Scientific Expert who shall jointly select a third Scientific Expert within five (5) Business Days after the last to occur of their respective

[*] Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portion.

appointments to arbitrate the referred matter. The Scientific Expert mutually agreed by the parties or, if the parties cannot agree, the third Scientific Expert' selected by the party-appointed Scientific Experts is referred to as the "Selected Scientific Expert". Purchaser and Seller shall instruct the Selected Scientific Expert to determine, as promptly as practicable but in no event later than thirty (30) days after such person's appointment (the "Determination Period") whether the disputed Milestone Event has occurred. The Selected Scientific Expert's determination shall be made based on the submission of documents by the parties unless the Selected Scientific Expert determines-that an oral hearing is necessary. The Selected Scientific Expert shall determine that which shall be conclusively deemed to be fair and appropriate deadlines within the Determination Period for submitting documents and dates, if any, of oral hearings. Each of Purchaser and Seller shall pay its own expenses of arbitration, and the fees, costs and expenses of the Selected Scientific Expert shall be equally shared between Purchaser and Seller. Any decision rendered by the Selected Scientific Expert shall be final and binding upon the parties. All proceedings conducted by the Selected Scientific Expert shall take place in New York, New York.

SECTION 1.03. Royalty Payments. Pursuant to Section 1.01(a)(iii), during the Royalty Term, royalty payments (the "Royalty Payments") shall be payable by Purchaser to Seller in accordance with this Section 1.03.

(a) Royalty Rates. Purchaser shall pay to Seller Royalty Payments of (i) [*] percent ([*]%) of annual worldwide Net Sales of the Product made directly by Purchaser or its Affiliates and (ii) [*] percent ([*]%) of annual worldwide Net Sales of the Product made directly or indirectly by Purchaser's Sublicensees.

(b) Royalty Term. The Royalty Payments shall be payable during the period commencing on the date of the First Commercial Sale of the Product in a country until the expiration of the last to expire Valid Claim of a Transferred Patent or any other patent issued after the date hereof covering the use or sale of the applicable Product in such country (the "Product Patent Rights") (such period being the "Royalty Term" for the Product in such country).

(c) Intercompany Sales. No Royalty Payments shall be due upon the sale or other transfer of the Product among Purchaser, its Affiliates or Sublicensees, but in such cases the Royalty Payments shall be calculated and payable in accordance with this Section 1.03 upon Purchaser's or its Affiliate's Net Sales of the Product to the first independent Third Party and upon sales of the Product to an independent Third Party by any Sublicensee of Purchaser.

SECTION 1.04. Royalty Records, Reporting and Payments.

(a) Royalty Report and Payment. During the Royalty Term, within sixty (60) days after the end of each Calendar Quarter, Purchaser shall pay to Seller the Royalty Payments payable for such Calendar Quarter and provide a royalty report showing, on a country-by-country basis:

(i) the Net Sales of the Product sold by Purchaser and any sale of the Product made by its Sublicensees and their respective Affiliates during such Calendar Quarter reporting period;

(ii) the Royalty Payments in Dollars which shall have accrued hereunder with respect to any sales of the Product;

(iii) withholding taxes, if any, required by applicable Law to be deducted with respect to such

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Royalty Payments; and

(iv) the rate of exchange, if applicable, used by Purchaser in determining the amount of Dollars payable hereunder.

If no Royalty Payment is due for any period during the Royalty Term, Purchaser shall so report. Purchaser shall keep, and shall require its Sublicensees and their respective Affiliates to keep (all in accordance with GAAP, consistently applied), complete and accurate records in sufficient detail to properly reflect the sales of the Product and each of the deductions to be applied to such sales in the calculation of Net Sales, and to enable the royalties payable hereunder to be determined.

(b) Manner of Payment And Exchange Rate. All payments to be made by Purchaser to Seller under Section 1.03 and this Section 1.04 shall be made in Dollars and shall be paid by electronic transfer in immediately available funds to such bank account in the United States designated in writing by Seller. In the case of sales of the Product outside the United States, the rate of exchange to be used in computing the amount of currency equivalent in Dollars payable shall be the rate of exchange used by Purchaser for its own financial reporting purposes in connection with its other products, which shall be consistent with GAAP. Upon request by Seller, Purchaser shall inform Seller regarding Purchaser's then-current currency exchange policy.

(c) Tax Withholding. Seller shall be liable for any and all taxes, duties and other levies applied by a government of any country of the Territory on payments made by Purchaser to Seller under Section 1.03 and this Section 1.04. In the event that any Royalty Payment or other payments due to Seller are subject to withholding tax required by Applicable Law to be paid to the taxing authority of any foreign country, Purchaser may deduct the amount of such tax paid from the applicable royalties or other payment otherwise payable to Seller. In such event, Purchaser shall, on a timely basis, notify Seller of such obligation, pay the taxes to the proper taxing authority and send evidence of the obligation together with proof of payment thereof to Seller following that payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any relevant agreement or treaty or convention which is in effect.

(d) Interest Due. Without limiting any other rights or remedies available to Seller, Purchaser shall pay Seller interest on any payments that are not paid on or before the date such payments are due under Section 1.03 and this Section 1.04 at a rate of one-and-one-half-percent (1.5%) per month or the maximum applicable legal rate,, if less, calculated on the total number of days payment is delinquent.

(e) Sales Record Audit. Purchaser shall keep, and shall cause each of its Affiliates and Sublicensees, if any, to keep, full and accurate books of accounting in accordance with GAAP containing all particulars that may be necessary for the purpose of calculating all Royalty Payments payable to Seller. Such books of accounting (including, without limitation, those of Purchaser's Affiliates and Sublicensees, if any) shall be kept at their principal place of business and, with all necessary supporting data, for the period of three (3) years following the end of the Calendar Year to which each shall pertain, and shall be open for inspection on an annual basis by an independent certified accountant selected by Seller, at its expense, for the purpose of verifying royalty statements for compliance with Section 1.03 and this Section 1.04. Such accountant must have agreed in writing to maintain all information learned in confidence, except as necessary to disclose to Seller such compliance or noncompliance by Purchaser. Seller shall pay for such inspections, except that in the event such accountant correctly determines that there is any upward adjustment in aggregate royalties payable for the Calendar Quarter period of such inspection of more than five percent (5%) of the amount,, paid, Purchaser shall pay for the reasonable out-of-pocket costs of such inspection. Any underpayments shall be paid by Purchaser within thirty (30) days of notification of the results of such inspection. Any overpayments shall be fully creditable by Purchaser against amounts payable in subsequent payment periods or, if no such amounts become payable within ninety (90) days after notification of such results, shall be refunded by Seller to Purchaser.

SECTION 1.05. Transfer of Assets.

(a) The term "Acquired Assets" means all of Seller's and the Selling Affiliates' right, title and interest in, to and under those certain assets identified below:

(i) the following (collectively, "Transferred Intellectual Property"):

(A) the patents, patent applications and statutory invention registrations of Seller and the Selling Affiliates identified in ' Section 1.05(a)(i)(A) of the Seller Disclosure Schedule, together' with any reissues, divisions, continuations, continuations-in-part, extensions, provisional or supplemental protection certificates, renewals and reexaminations thereof (the "Transferred Patents");

(B) the trademark registrations, trademark applications, service mark registrations, service mark applications and domain name registrations of Seller and the Selling Affiliates identified in Section 1.05(a)(i)(B) of the Seller Disclosure Schedule, together. with all extensions and renewals thereof and all goodwill associated therewith;

(C) the copyright registrations of Seller and the Selling Affiliates identified in Section I .05(a)(i)(C) of the Seller Disclosure Schedule, together with all extensions and renewals thereof; and

(D) all Product Formulae and Manufacturing Knowhow of. Seller and the Selling Affiliates (collectively "Technology") that are exclusively related to the Product, in each case to the extent transferable in light of legal, contractual and practical considerations;

provided, however, that Transferred Intellectual Property shall not include any Excluded Intellectual Property;

(ii) all raw materials (including all bulk active pharmaceutical ingredients for the Product), work-in-progress, components, supplies and other inventories (including items in transit, on consignment, or covered by open purchase orders or in the possession of any third party) used or held for use by Seller and the Selling Affiliates solely in, or arise solely out of, the conduct of the Business on the Closing Date, to the extent transferable in light of legal, contractual and practical considerations (collectively, the "Transferred Inventory"); *provided, however,* that Transferred Inventory shall not include any Excluded Inventory;

(iii) all contracts, leases, subleases, indentures, licenses, agreements, commitments and all other legally binding arrangements (including binding purchase orders outstanding as of the Closing Date), whether written or oral ("Contracts"), to which Seller or any of the Selling Affiliates is a party or by which any of the Acquired Assets is bound, that are used solely in, or related solely to, the conduct of the Business, including the Contracts set forth in Section 4.06 of the Seller Disclosure Schedule, and in each case to the extent transferable in light of legal, contractual and practical considerations (the "Transferred Contracts"); *provided, however,* that Transferred Contracts shall not include any Excluded Contract;

(iv) all licenses, permits, authorizations and approvals (including NDAs, BLAs and MAAs, if any) from any Governmental Entity (other than Environmental Permits) ("Permits") of Seller and the Selling Affiliates that are used solely in the conduct of the Business or related solely to any of the Acquired Assets, including the Permits identified in Section 1.05(a)(iv) of the Seller Disclosure Schedule, to the extent transferable in light of legal, contractual and' practical considerations (the "Transferred Permits"); *provided, however,* that Transferred Permits shall not include any Excluded Permit;

(v) all Environmental Permits of Seller and the Selling Affiliates that are used solely in the conduct of the Business, including the Environmental Permits identified in Section 1.05(a)(v) of the Seller Disclosure Schedule (the "Transferred Environmental Permits"); *provided, however,* that Transferred Environmental Permits shall not include any Excluded Environmental Permits;

(vi) all books and records (or portions of books and records), including laboratory books, and preclinical and clinical studies lists, (in all cases, in any form or medium) ("Records") of Seller and the Selling Affiliates that relate solely to, or that arise solely out of, the conduct of the Business, in each case in existence on the Closing Date and within the possession and control of

Seller and to the extent transferable in light of legal, contractual and practical considerations (the "Transferred Records"); *provided, however,* that Transferred Records shall not include any Excluded Records;

(vii) all proprietary rights of Seller and the Selling Affiliates to the information, materials, data and work product proprietary to Seller or any of the Selling Affiliates in respect of research and development activities and preclinical and clinical trials conducted or being conducted solely for use in connection with the conduct of the Business, in each case to the extent transferable in light of legal, contractual and practical considerations; and

(viii) all tangible personal property and interests therein, including equipment and furnishings ("Personal Property"), of Seller and the Selling Affiliates listed in Section 1.05(a)(viii) of the Seller Disclosure Schedule (the "Transferred Personal Property").

(b) The term "Excluded Assets" means:

(i) all cash and cash equivalents of Seller, and any of its Affiliates;

(ii) all Accounts Receivable;

(iii) (A) all intellectual property of Seller and any of its Affiliates, other than the Transferred Intellectual Property, including the intellectual property identified in Section 1.05(b)(iii) of the Seller Disclosure Schedule and (B) all Technology of Seller and its Affiliates other than the Technology included in the Transferred Intellectual Property, including all Product Formulae, Manufacturing Knowhow and packaging specifications which are not exclusively related to the Product (collectively, the "Excluded Intellectual Property");

(iv) all raw materials, work-in-process, finished goods, supplies, part's, spare parts and other inventories of Seller and its Affiliates other than the Transferred Inventory, including the items identified in Section 1.05(b)(iv) of the '• Seller Disclosure Schedule (the "Excluded Inventory");

(v) all credits, deferred charges, and prepaid items of Seller or any of its Affiliates (the "Excluded Miscellaneous Rights");

(vi) all Contracts, including the Contracts identified in Section 1.05(b)(vi) of the Seller Disclosure Schedule, to which Seller or any of its Affiliates is a party other than the Transferred Contracts described in Section 1.05(a)(iii) (the "Excluded Contracts");

(vii) all Permits of Seller or any of its Affiliates other than the Transferred Permits (the "Excluded Permits") and all Environmental Permits of the Seller or any of its Affiliates other than the

Transferred Environmental Permits (the "Excluded Environmental Permits");

(viii) all of the following: (A) any and all books and records prepared and maintained by Seller or any of its Affiliates, including financial records, laboratory books, batch records and stability studies, that do not relate exclusively to the Product, (B) any and all Tax records that relate to Taxes that constitute Excluded Tax Liabilities, (C) any and all records to the extent related to any Excluded Assets or Excluded Liability, (D) any and all books and records prepared in connection with the transactions contemplated by this Agreement, including bids received from other parties and analyses relating to the Product, and (E) any and all books and records, files, correspondence or other Records of Seller or its Affiliates other than the Transferred Records, (collectively, the "Excluded Records");

(ix) all rights, claims and credits of Seller or any of its Affiliates to the extent relating to any Excluded Asset or any Excluded Liability, including any such items arising under insurance policies and all guarantees, warranties, indemnities and similar rights in favor of Seller and its Affiliates in respect of any other Excluded Asset or any Excluded Liability;

(x) any refund or credit of Taxes attributable to any Excluded Tax Liability;

(xi) all insurance policies and insurance contracts insuring the Product or the Acquired Assets, together with any claim, action or other right Seller or any of its Affiliates might have for insurance coverage under any past and present policies and insurance contracts insuring the Product or the Acquired Assets, in each case including any proceeds received from any such policy or contract prior to, on or after the Closing Date;

(xii) all rights of Seller and its Affiliates under this Agreement, the Other Transaction Documents and the other agreements and instruments executed and delivered in connection with this Agreement;

(xiii) all land, buildings, improvements and fixtures thereon owned or leased by Seller or any of its Affiliates, including the leaseholds, sub-leaseholds and other interests in real property listed in Section 1.05(b)(xiii) of the Seller Disclosure Schedule;

(xiv) all tangible personal property and other fixed assets and interests therein, including all equipment, furnishings, furniture and fixtures, owned or leased by Seller or any of its Affiliates, including the tangible personal property and other fixed assets and interests therein, including all equipment, furnishings, furniture and fixtures listed in Section 1.05(b)(xiv) of the Seller Disclosure Schedule, and any warranty rights applicable to such tangible personal property, fixed assets and equipment other than the Transferred Personal Property (the "Excluded Personal Property");

(xv) the BMS Names; and

(xvi) except to the extent identified in a subsection of Section 1.05(a) of the Seller Disclosure Schedule as included in the Acquired Assets, all other properties, assets, goodwill and rights of Seller, the Selling Affiliates and any of their respective Affiliates of whatever kind and nature, real, personal or mixed, tangible or intangible, that are not used, held for use or intended to be used exclusively in connection with, or that do not arise exclusively out of, the Product or the Acquired Assets.

SECTION 1.06. Assumed Liabilities. (a) Upon the terms and subject to the conditions of this Agreement, Purchaser shall assume, effective as of 12:00:01 a.m. on the Closing Date, and from and after the

Closing Purchaser shall pay, perform and discharge when due, all of the following liabilities, obligations and commitments ("Liabilities") of Seller and the Selling Affiliates, other than any Excluded Liability (the "Assumed Liabilities"):

(i) all Accounts Payable, accrued expenses and other current liabilities arising out of or relating to the Product, the Acquired Assets or the Business arising on or after the Closing Date;

(ii) all Liabilities in respect of any lawsuits, claims, actions or proceedings arising out of or relating to the manufacture, production, marketing, commercialization, distribution or sale of the Product or the ownership, sale, lease or use of any of the Acquired Assets prior to, on or after the Closing Date;

(iii) all Liabilities for warranty claims and product liability or similar claims, including all suits, actions or proceedings relating to any such Liabilities, arising out of or relating to the Product) whether arising prior to, on or after the Closing Date;

(iv) all Liabilities for Taxes arising out of or relating to or in respect of the Product or any Acquired Asset for any Post-Closing Tax Period, other than any Excluded Tax Liabilities;

(v) all Liabilities for transfer, documentary, sales, use, registration, value added and other similar Taxes and related amounts (including any penalties, interest and additions to Tax) incurred in connection with this Agreement, any of the Other Transaction Documents, the Acquisition and the other transactions contemplated hereby and thereby ("Transfer Taxes");

(vi) all Environmental Liabilities to the extent arising out of or relating to the conduct of the Business or the Acquired Assets or the ownership, sale or lease of any of the Acquired Assets, whether arising prior to, on or after the Closing Date;

(vii) all Liabilities under or otherwise to the extent arising out of or relating to the Transferred Permits, whether arising prior to, on or after the Closing Date; and

(viii) all other Liabilities of Seller and the Selling Affiliates of whatever kind and nature, primary or secondary, direct or indirect, absolute or contingent, known or unknown, whether or not accrued, arising out of or relating to the conduct of the Business, the Product or Acquired Assets or the ownership, sale or lease of any of the Acquired Assets, whether arising prior to, on or after the Closing Date, including any claim, action, suit, arbitration, inquiry, proceeding or investigation by or before any Governmental Entity.

(b) Notwithstanding any other provision of this Agreement, Purchaser shall not assume any Excluded Liability, each of which shall be retained and paid, performed and discharged when due by Seller and the Selling Affiliates. The term "Excluded Liability" means:

(i) all Liabilities, to the extent related to or arising out of any Excluded Asset;

(ii) any Tax payable with respect to any business, asset, property or operation of Seller or its Affiliates (including any Taxes relating to or arising out of the Acquired Assets) for any Pre-Closing Tax Period, other than any Tax for which Purchaser is responsible pursuant to Section 8.07 ("Excluded Tax Liability"); and

(iii) all Accounts Payable other then the accounts payable, accrued expenses and other current liabilities assumed pursuant to Section 1.06(a)(i).

(c) Each of Purchaser's and Seller's obligations under this Section 1.06 will not be subject to offset or reduction by reason of any actual or alleged breach of any representation, warranty, covenant or agreement contained in this Agreement or any Other Transaction Document or any right or alleged right to indemnification hereunder;

SECTION 1.07. Risk of Loss. Until the Closing, any loss of or damage to the Acquired Assets from fire, casualty or any other occurrence shall be the sole responsibility of Seller or the Selling Affiliates, as applicable. On the Closing Date, title, to the Acquired Assets shall be transferred to Purchaser and Purchaser shall thereafter bear all risk of loss associated with the Acquired Assets and be solely responsible for procuring adequate insurance to protect the Acquired Assets against any such loss; provided that Purchaser's responsibility is not contingent on Purchaser's ability to procure adequate insurance.

SECTION 1.08. Consents of Third Parties. (a) Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign any asset (including any Contract or Permit) or any claim, right or benefit arising under or resulting from any such asset (including any Contract or Permit), claim, right or benefit arising under or resulting from such asset (including any Contract or Permit) if the assignment or transfer thereof, without the consent of a third party, would constitute a breach or other contravention of the rights of such third party, would be ineffective with respect to any party to an agreement concerning such asset (including any Contract or Permit), claim, right or benefit, or, upon assignment or transfer, would in any way adversely affect the rights of Seller or any Selling Affiliate or, upon transfer, Purchaser. If any transfer or assignment by Seller or any Selling Affiliate to, or any assumption by Purchaser of, any interest in, or liability, obligation or commitment under, any asset (including any Contract or Permit), or any claim, right or benefit requires the consent of a third party, then such transfer or assumption shall be made subject to such consent being obtained.

(b) If any such consent is not obtained prior to the Closing, Seller, the Selling Affiliates and Purchaser shall cooperate (each at their own expense) in any lawful and reasonable arrangement reasonably proposed by Purchaser under which Purchaser shall obtain the economic claims, rights and benefits under the asset (including any Contract or Permit) or related claim, right or benefit with respect to which the consent has not been obtained in accordance with this Agreement. Such reasonable arrangement may include (i) the subcontracting, sublicensing or subleasing to Purchaser of any and all rights of Seller and the Selling Affiliates against the other party to such third-party agreement arising out of a breach or cancellation thereof by the other party and (ii) the enforcement by Seller or the Selling Affiliates of such rights.

(c) Notwithstanding that the laptops, desktops and other computer hardware included as part of the Transferred Personal Property have (and will at closing have) installed on them certain Seller and third party operating systems and software Purchaser hereby acknowledges and agrees that the Acquired Assets do not include ownership of, or any licenses or other rights to use, any such operating systems or software, and that Seller has not and does not intend to complete a software license or other transfer with respect to any such operating systems or software. Purchaser further agrees that it shall be fully responsible for obtaining any and all licenses or other rights required to continue to use such operating systems and software, and to otherwise comply with all applicable laws, in each case from and after the Closing Date.

SECTION 1.09. Refunds and Remittances. (a) Received by Seller or the Selling Affiliates. After the Closing, if Seller or any of the Selling Affiliates receives (i) any refund or other amount which is an Acquired Asset or is otherwise properly due and owing to Purchaser in accordance with the terms of this Agreement, or (ii) any refund or other amount which is related to claims or other matters for which Purchaser is responsible hereunder, and which amount is not an Excluded Asset, or is otherwise properly due and owing to Purchaser in

accordance with the terms of this Agreement, Seller promptly shall remit, or shall cause to be remitted, such amount to Purchaser at the address set forth in Section 11.06(a).

(b) Received by Purchaser or its Affiliates. After the Closing, if Purchaser or any of its Affiliates receives (i) any refund or other amount which is an Excluded Asset or is otherwise properly due and owing to Seller or any of the Selling Affiliates in accordance with the terms of this Agreement, or (ii) any refund or other amount which is related to claims or other matters for which Seller is responsible hereunder, and which amount is not an Acquired Asset, or is otherwise properly due and owing to Seller in accordance with the terms of this Agreement, Purchaser promptly shall remit, or shall cause to be remitted, such amount to Seller at the address set forth in Section 11.06(b).

ARTICLE II

Closing

SECTION 2.01. Closing. (a) The closing of the Acquisition (the "Closing") shall take place on the date hereof and shall be held at the offices of the Seller, Route 206 & Province Line Road, Princeton, New Jersey. The date on which the Closing shall occur is hereinafter referred to as the "Closing Date". For purposes of this Agreement, the Closing shall be deemed effective at 12:00:01 a.m. on the Closing Date.

(b) At the Closing, Purchaser shall deliver to the Seller:

(i) by wire transfer to a bank account designated in writing by Seller at least two (2) business days prior to the Closing Date in United States Dollars, immediately available funds in an amount equal to the Base Purchase Price;

(ii) the Assumption Agreement and such other instruments of assumption and such other instruments and documents as Seller or the Selling Affiliates may reasonably request to effect or evidence the purchase of the Acquired Assets and the assumption of the Assumed Liabilities;

(iii) an executed counterpart of the IP Assignment Documents with respect to the Transferred. Intellectual Property; and

(iv) the certificate required to be delivered by Purchaser under Section 3.02(a) duly executed by an authorized officer of Purchaser.

(c) At the Closing, Seller shall deliver to Purchaser:

(i) a receipt for the Base Purchase Price paid by Purchaser;

(ii) the Bill of Sale and such other instruments and documents as Purchaser may reasonably request to effect or evidence the transfer to Purchaser of the Acquired Assets;

(iii) an executed counterpart of the IP Assignment Documents with respect to the Transferred Intellectual Property; and

(iv) the certificate required to be delivered by Seller under Section 3.02(a) duly executed by an authorized officer of Seller.

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

ARTICLE III

Conditions to Closing

SECTION 3.01. Conditions to Obligations of Purchaser. The obligation of Purchaser to effect the transactions contemplated by this Agreement is subject to the satisfaction (or written waiver by Purchaser) as of the Closing of the following conditions:

(a) Representations and Warranties: Covenants. The representations and warranties of Seller made in this Agreement shall be true and correct in all material respects as of the time of the Closing as though made as of such time, except to the extent such representations and warranties expressly relate to an earlier date (in which case .such representations and warranties shall be true and correct in all material respects as of such earlier date), in each case except for breaches as to matters that, individually or in the aggregate, would not be reasonably likely to have a Material Adverse Effect. Seller shall, have performed or complied in all material respects with all obligations and covenants required by this Agreement to be performed or complied with by Seller by the time of the Closing. Seller shall have delivered to Purchaser a certificate dated the Closing Date and signed by an authorized officer of Seller confirming the foregoing.

(b) No Injunctions or Restraints. No statute, rule, regulation, executive order, decree, temporary restraining order, preliminary or permanent injunction or other order enacted, entered, promulgated, enforced or issued by any Federal, state or local government or any court of competent jurisdiction, administrative or regulatory agency or commission or other governmental authority or instrumentality, including the FDA, the EMEA or any successor agency thereto which has the responsibility over the development and commercialization of the Product (a "Governmental Entity"), or other legal restraint or prohibition shall be in effect preventing the Acquisition.

(c) Other Transaction Documents. Seller shall have executed and delivered to Purchaser the Other Transaction Documents to which Seller is a party and each Selling Affiliate shall have executed and delivered to Purchaser the Other Transaction Documents to which such Selling Affiliate is specified to be a party.

SECTION 3.02. Conditions to Obligation of Seller. The obligation of Seller to, or to cause the Selling Affiliates to, effect the transactions contemplated by this Agreement is subject to the satisfaction (or written waiver by Seller) as of the Closing of the following conditions:

(a) Representations and Warranties; Covenants. The representations and warranties of Purchaser made in this Agreement shall be true and correct in all material respects as of the time of the Closing as though made as of such time, except to the extent such representations and warranties expressly relate to an earlier date (in which case such representations and warranties shall be true and correct in all material respects as of such earlier date), in each case except for breaches as to matters that, individually or in the aggregate, would not be reasonably likely to have a material adverse effect on the ability of Purchaser to consummate the transactions contemplated hereby. Purchaser shall have performed or complied in all material respects with all obligations and covenants required by this Agreement to be performed or complied with by Purchaser by the time of the Closing. Purchaser shall have delivered to Seller a certificate dated the Closing Date and signed by an authorized officer of Purchaser confirming the foregoing.

(b) No Injunctions or Restraints. No statute, rule, regulation, executive order, decree, temporary restraining order, preliminary or permanent injunction or other order enacted, entered, promulgated, enforced or issued by any Governmental Entity, or other legal restraint or prohibition shall be in effect preventing the Acquisition.

(c) Other Transaction Documents. Purchaser shall have executed and delivered to Seller the

Other Transaction Documents to which Purchaser is a party.

SECTION 3.03. Frustration of Closing Conditions. Neither Purchaser nor Seller may rely on the failure of any condition set forth in this Article III to be satisfied if such failure was caused by such party's failure to act in good faith or to use its best efforts to cause the Closing to occur, as required by Section 8.04.

ARTICLE IV

Representations and Warranties of Seller

Except as set forth in the Seller Disclosure Schedule attached hereto (the "Seller Disclosure Schedule"), Seller hereby represents and warrants to Purchaser as follows:

SECTION 4.01. Authority. Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Each Selling Affiliate is a legal entity, duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization. Seller has all requisite corporate power and authority to enter into this Agreement, and Seller and each of the Selling Affiliates has all requisite corporate power and authority to enter into the Other Transaction Documents to which it is, or is specified to be, a party and to consummate the transactions contemplated hereby and thereby. All corporate acts and other proceedings required to be taken by Seller and each of the Selling Affiliates to authorize the execution, delivery and performance of this Agreement and the Other Transaction Documents to which it is, or is specified to be, a party and to consummate the transactions contemplated hereby and thereby have been duly and properly taken. This Agreement has been duly executed and delivered by Seller and, assuming this Agreement has been duly authorized, executed and delivered by Purchaser, constitutes, and the Other Transaction Documents on the Closing Date will be duly executed and delivered by Seller or the Selling Affiliates, as applicable, and upon the due authorization, execution and delivery by each other party to the Other Transaction Documents will constitute, a legal, valid and binding obligation of such person, enforceable against such person in accordance with its terms, subject, as to enforcement, to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally and to general equitable principles.

SECTION 4.02. No Conflicts: Consents. (a) The execution and delivery of this Agreement by Seller do not, and the execution and delivery of the Other Transaction Documents by Seller and the Selling Affiliates specified to be parties thereto will not, and the consummation of the transactions contemplated hereby and thereby and compliance with the terms and conditions hereof and thereof will not, conflict with, or _ result in any violation of or default (with or without notice or lapse of time, or both) , under, or give rise to a right of termination, cancellation or acceleration of any obligation or loss of a material benefit under, or result in the creation of any liens, claims, encumbrances, security interests, options, charges or restrictions of any kind ("Liens") upon any of the Acquired Assets under, any provision of (i) the certificate of incorporation or by-laws (or the comparable governing instruments) of Seller or any Selling Affiliate, (ii) any Contract, or (iii) any judgment, order or decree, or, subject to the matters referred to in clauses (i) and (ii) of paragraph (b) below, Applicable Law applicable to Seller or any Selling Affiliate or the Acquired Assets, other than, in the case of clauses (ii) and (iii) above, any such items that, individually or in the aggregate, would not be reasonably likely to have a Material Adverse Effect.

(b) No material consent, approval, license, permit, order or authorization of, or registration, declaration or filing with, any Governmental Entity is required to be obtained or made by or with respect to Seller or any Selling Affiliate in connection with the execution, delivery and performance of this Agreement, the Other Transaction Documents or the consummation of the transactions contemplated hereby or thereby other than (i) those that may be required solely by reason of Purchaser's or any Affiliate of Purchaser's (as opposed to

any other third party's) participation in the -transactions contemplated hereby or by the Other Transaction Documents and (ii) such consents, approvals, licenses, permits, orders, authorizations, registrations, declarations and filings the absence of which, or the failure to make or obtain which, individually or in the aggregate, would not be reasonably likely to have a Material Adverse Effect.

SECTION 4.03. Taxes. (a) For purposes of this Agreement, (i) "Tax" or "Taxes" shall mean all Federal, state, local and foreign taxes and similar assessments (other than Transfer Taxes), including all interest, penalties and additions imposed with respect to such amounts; (ii) "Pre-Closing Tax Period" shall mean all taxable periods ending on or before the Closing Date and the portion ending on the Closing Date of any taxable period that includes (but does not end on) the Closing Date; (iii) "Post-Closing Tax Period" shall mean all taxable periods beginning and ending after the Closing Date and the portion beginning on the day after the Closing Date of any Straddle Period; and (iv) "Code" shall mean the U.S. Internal Revenue Code of 1986, as amended.

(b) No material Tax liens have been filed and no material claims are being asserted in writing with respect to any Taxes due with respect to the Acquired Assets.

SECTION 4.04. Good and Valid Title. Seller and the Selling Affiliates have, or as of the Closing Date will have, good and valid title to all material Acquired Assets (other than Transferred Inventory covered by open purchase orders), in each case free and clear of all Liens, except (i) such as are set forth in Section 4.04 of the Seller Disclosure Schedule; (ii) mechanics', carriers', workmen's, repairmen's or other like Liens arising or incurred in the ordinary course of business, Liens arising under original purchase price conditional sales contracts and equipment leases with third parties entered into in the ordinary course of business and Liens for Taxes and other governmental charges which are not due and payable or which may thereafter be paid without penalty; and (iii) other imperfections of title or encumbrances, if any, which do not, individually \ or in the aggregate, materially impair the continued use and operation of the Acquired Assets to which they relate (the Liens described in clauses (i), (ii) and (iii) above are hereinafter referred to collectively as "Permitted Liens"). This Section 4.04 does not relate to Intellectual Property or Contracts, such items being the subjects of Section 4.06 and Section 4.07, respectively.

SECTION 4.05. Intellectual Property. (a) Except as set forth in Section'4.05 of the Seller Disclosure Schedule, Seller or a Selling Affiliate owns, or as of the Closing Date will own, free and clear of all Liens (except to the extent the Transferred N Intellectual Property may be licensed from third parties), the material Transferred Intellectual Property and the consummation of the transactions contemplated hereby will not conflict with, alter or impair any such rights in any material respect. The Transferred Intellectual Property constitutes all of the Intellectual Property owned by or in-licensed by Seller relating solely to the Product. As of the date of this Agreement, no claims are pending or, to the knowledge of Seller, threatened in writing, against Seller or any of its Affiliates by any person with respect to the ownership, validity or enforceability of any material Transferred Intellectual Property.

(b) Except as set forth in Section 4.05 of the Seller Disclosure Schedule, none of Seller or the Selling Affiliates has granted any material options, licenses or agreements relating to the Transferred Intellectual Property, except non-exclusive implied licenses to end-users in the ordinary course of business. To the knowledge of Seller, none of Seller or the Selling Affiliates as of the date hereof is bound by or a party to any material options, licenses or agreements of any kind constituting part of the Acquired Assets relating to the intellectual property of any other person, except for agreements relating to computer software licensed to Seller or its Affiliates in the ordinary course of business.

(c) To the knowledge of Seller, there are no patents, patent applications or statutory registrations

of Seller or the Selling Affiliates which were owned by Inhibitex as of closing date of the acquisition of Inhibitex by Seller (i.e., February 13, 2012) and relate solely to the Product which are not included as part of the Transferred Patents.

SECTION 4.06. Contracts. (a) Section 4.06 of the Disclosure Schedule sets forth each Transferred Contract that is or contains:

(i) a covenant by Seller or a Selling Affiliate not to compete (other than pursuant to any radius restriction contained in any lease, reciprocal easement or development, construction, operating or similar agreement) or other covenant restricting the research, development, manufacture, marketing or distribution of the Product that materially impairs the such activities as the Business is currently conducted;

(ii) an agreement, contract or other arrangement with Seller or any Affiliate of Seller; *provided, however,* that the foregoing shall be deemed not to include any Other Transaction Document or any agreement, contract or other arrangement that will expire or be terminated at or prior to Closing;

(iii) (A) a continuing contract for the future purchase of materials, supplies or equipment (other than purchase contracts and orders for inventory in the ordinary course of business consistent with past practice); (B) a management, service, consulting or other similar type of contract (other than contracts for services in the ordinary course of business) or (C) an advertising agreement or arrangement, in any such case which has an aggregate future liability to any person in excess of $100,000 and is not terminable by Seller or such Selling Affiliate, as applicable, by notice of not more than one hundred and eighty (180) days for a cost of less than $100,000;

(iv) a material license, option or other agreement relating in whole or in part to the Transferred Intellectual Property (including any license or other agreement under which Seller or a Selling Affiliate is licensee or licensor of any such Transferred Intellectual Property); or

(v) any other agreement, contract, lease, license, commitment or instrument to which Seller or a Selling Affiliate is a party and by or to which any of the Product or the Acquired Assets or business is bound or subject which has an aggregate future liability to any person in excess of $100,000 and is not terminable by Seller or such Selling Affiliate, as applicable, by notice of not more than one hundred and eighty (180) days for a cost of less than $100,000.

(b) Except as set forth in Section 4.06 of the Seller Disclosure Schedule, each Transferred Contract set forth in Section 4.06 of the Seller Disclosure Schedule is valid, binding and in full force and effect and, to the knowledge of Seller, is enforceable by Seller or the applicable Selling Affiliate in accordance with its terms, subject to applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and other laws affecting creditors' rights generally, general principles of equity and the discretion of courts in granting equitable remedies and except to the extent that the failure of a Transferred Contract to be valid, binding and in full force and effect would not be reasonably likely to have a Material Adverse Effect. Seller and the Selling Affiliates have performed in all material respects all material obligations required to be performed by them to date under the Transferred Contracts and is not (with or without the lapse of time or the giving of notice, or both) in breach or default in any material respect thereunder and, to the knowledge of Seller, no other party to any of the Transferred Contracts set forth in Section 4.06 of the Seller Disclosure Schedule, as of the date of this Agreement, is (with or without the lapse of time or the giving of notice, or both) in breach or default in any material respect thereunder, except to the extent that such breach or default would not be reasonably likely to have a Material Adverse Effect.

SECTION 4.07. Transferred Permits. All Transferred Permits are validly held by Seller or the

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Selling Affiliates, and Seller or the applicable Selling Affiliate has complied in all material respects with all terms and conditions thereof, except for any such invalidity or non-compliance that would not be reasonably likely to have a Material Adverse Effect. During the past three (3) years, none of Seller or the Selling Affiliates has received written notice of any suit, action or proceeding relating to the revocation or modification of any Transferred Permit the loss of which, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

SECTION 4.08. Litigation. Section 4.08 of the Seller Disclosure Schedule sets forth a list of all lawsuits or claims pending as of the date of this Agreement, with respect to which Seller or any Selling Affiliate has been contacted in writing by counsel for the plaintiff or claimant, against any Acquired Asset and which (a) involve an uninsured claim of, or which involve an uninsured unspecified amount which would reasonably be expected to result in a liability of, more than $100,000, (b) seek any material injunctive relief or (c) seek any legal restraint on or prohibition against the transactions contemplated by this Agreement. To the knowledge of Seller, as of the date of this Agreement, none of Seller or the Selling Affiliates is a party or subject to or in default under any material judgment, order, injunction or decree of any Governmental Entity or arbitration tribunal applicable to the Product or any material Acquired Asset.

SECTION 4.09. Compliance with Applicable Laws. Seller and the Selling Affiliates are in compliance in all material respects with all applicable statutes, laws, ordinances, rules, orders and regulations of any Governmental Entity ("Applicable Laws"), including those relating to occupational health and safety, except for instances of noncompliance that, individually or in the aggregate, would not be reasonably likely to have a Material Adverse Effect. None of Seller or any Selling Affiliate has received during the two (2) years prior to the date hereof any written communication from a Governmental Entity that alleges that Seller or any Selling Affiliate is in violation of any Applicable Laws except for any such violations that, individually or in the aggregate; would not be reasonably likely to have a Material Adverse Effect. This Section 4.09 does not relate to matters with respect to Taxes, which are the subject of Section 4.03, or environmental matters, which are the subject of Section 4.10.

SECTION 4.10. Environmental Matters. Except as set forth in Section 4.10 of the Seller Disclosure Schedule, and except as would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect, (a) Seller and the Selling Affiliates (in each case solely to the extent related to the Business or the Acquired Assets) and the Acquired Assets are in compliance with all applicable Environmental Laws, (b) none of Seller or any Selling Affiliate has received since January 1, 2012, and prior to the date hereof, any written communication from a Governmental Entity that alleges that Seller or any Selling Affiliate is in violation of any applicable Environmental' Law in connection with the conduct of the Business, the substance of which communication has not been resolved, or that it is a potentially responsible party under the Federal Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA") (in each case, solely to the extent related to the Business or Acquired Assets), and (c) there are no pending or, to the knowledge of Seller, threatened lawsuits, actions, arbitrations, claims, complaints or other proceedings against Seller or any Selling Affiliate relating to non-compliance with applicable Environmental Laws, to exposure to Hazardous Materials (including any exposure of any Transferred Employee or independent contractor of the Business to Hazardous Materials) or to a Release of Hazardous Material (in each case, solely to the extent related to the Business or the Acquired Assets). Except as specifically provided in Section 4.02, the representations and warranties made in this Section 4.10 are Seller's exclusive representations and warranties relating to environmental matters.

SECTION 4.11. Absence of Changes or Events. Subject to the matters set forth in the Seller Disclosure Schedule, including Section 4.11 thereof, since January 1, 2012, there has not been any event, occurrence or development that has resulted in a Material Adverse Effect. Purchaser acknowledges that there has been and will continue. to be a disruption to the conduct of the Business as a result of the announcement by Seller of its intention to sell the Product and the Acquired Assets and as a result of the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, and Purchaser agrees that such disruptions do not and shall not constitute a breach of this Section 4.11 or of Section 5.02.

SECTION 4.12. DISCLAIMER. PURCHASER ACKNOWLEDGES THAT EXCEPT AS SET FORTH IN THIS ARTICLE IV, NEITHER SELLER NOR ANY OTHER PERSON HAS MADE ANY REPRESENTATION OR WARRANTY, EXPRESSED OR IMPLIED, AS TO THE ACQUIRED ASSETS, THE PRODUCT, ANY OTHER ASPECT OF THE RESPECTIVE BUSINESSES OF SELLER AND THE SELLING AFFILIATES, OR THE ACCURACY AND COMPLETENESS OF ANY INFORMATION REGARDING THE ACQUIRED ASSETS FURNISHED OR MADE AVAILABLE TO PURCHASER AND ITS REPRESENTATIVES AND PURCHASER HAS NOT RELIED ON ANY REPRESENTATION FROM SELLER OR ANY OTHER PERSON WITH RESPECT TO THE ACQUIRED ASSETS, THE PRODUCT, ANY ASPECT OF THE RESPECTIVE BUSINESSES OF SELLER AND THE SELLING AFFILIATES, OR THE ACCURACY OR COMPLETENESS OF ANY INFORMATION REGARDING THE ACQUIRED ASSETS FURNISHED OR MADE AVAILABLE TO PURCHASER AND ITS REPRESENTATIVES IN DETERMINING TO ENTER INTO THIS AGREEMENT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE IV. PURCHASER ACKNOWLEDGES THAT SHOULD THE CLOSING OCCUR, PURCHASER SHALL ACQUIRE THE ACQUIRED ASSETS WITHOUT ANY REPRESENTATION AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IN AN “AS IS” CONDITION AND ON A “WHERE IS” BASIS AND PURCHASER SHALL BEAR THE ECONOMIC AND LEGAL RISKS THAT ANY CONVEYANCE SHALL PROVE TO BE INSUFFICIENT TO VEST IN THE PURCHASERS GOOD AND MARKETABLE TITLE, FREE AND CLEAR OF ANY LIENS, THAT ANY NECESSARY CONSENTS OR GOVERNMENTAL APPROVALS ARE NOT OBTAINED AND THAT ANY REQUIREMENTS OF APPLICABLE LAWS OR JUDGMENTS ARE NOT COMPLIED WITH.

ARTICLE V

Covenants of Seller

Seller covenants and agrees as follows:

SECTION 5.01. Access. From the date hereof to the Closing, Seller shall, and shall cause the Selling Affiliates to, give Purchaser and its representatives, employees, counsel and accountants reasonable access, during normal business hours and upon reasonable advance notice, to the Acquired Assets; *provided, however,* that such access (i) does not unreasonably disrupt the normal operations of Seller or the Selling Affiliates, (ii) would not be reasonably expected to violate any attorney-client privilege of Seller or the Selling Affiliates or violate any Applicable Law and (iii) would not reasonably be expected to breach any duty of confidentiality owed to any person whether the duty arises contractually, statutorily or otherwise.

SECTION 5.02. Ordinary Conduct. (a) Except as set forth in Section 5.02 of the Seller Disclosure Schedule or otherwise contemplated by the terms of this Agreement, from the date hereof until the Closing, Seller shall, and shall cause the Selling Affiliates to, cause the distribution and sale of the Product to be conducted in all material respects in the ordinary course in substantially the same manner as conducted as of the date hereof and shall make all reasonable efforts consistent with current practices to preserve the relationships with customers, suppliers, distributors and others with whom the Seller or Selling Affiliates has a material business relationship with respect to the Product.

(b) Except as set forth on Section 5.02 of the Seller Disclosure Schedule or otherwise contemplated by the terms of this Agreement, Seller shall not, and shall not permit any Selling Affiliate to, do any of the following in connection with the Acquired Assets without the prior written consent of Purchaser:

(i) permit, allow or suffer any Acquired Asset to become subjected to any Lien of any nature whatsoever which would have been required to be set forth in Section 4.04 or 4.06 of the Seller Disclosure Schedule if it existed on the date of this Agreement;

(ii) sell, lease or otherwise dispose of any Acquired Assets which are material, individually or in the aggregate, to the Product, except for sales of raw materials, work-in-process, finished goods, supplies and other inventories in the ordinary course of business;

(iii) terminate, modify or amend in any material respect any Transferred Contract or Transferred Permit; or

(iv) agree, whether in writing or otherwise, to do any of the foregoing., SECTION 5.03. Transferred Intellectual Property. Except as otherwise contemplated by Section 8.02, from and after the Closing, none of Seller nor the Selling Affiliates shall make any filings with any Governmental Entity relating to the Transferred Intellectual Property, nor grant or attempt to grant any material options, licenses or agreements relating to the Transferred Intellectual Property.

ARTICLE VI

Representations and Warranties of Purchaser

Purchaser hereby represents and warrants to Seller as follows:

SECTION 6.01. Authority. Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Purchaser has all requisite corporate power and authority to enter into this Agreement and the Other Transaction Documents to which it is, or is specified to be, a party and to consummate the transactions contemplated hereby and thereby. All corporate acts and other proceedings required to be taken by Purchaser to authorize the execution, delivery and performance of this Agreement and the Other Transaction Documents to which it is, or is specified to be, a party and to consummate the transactions contemplated hereby and thereby have been duly and properly taken. This Agreement has been duly executed and delivered by Purchaser and, assuming this Agreement has been duly authorized, executed and delivered by Seller, constitutes, and the Other Transaction on the Closing Date will be duly executed by Purchaser, and upon the due authorization, execution and delivery by each other party to the Other Transaction Documents, will constitute a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, subject, as to enforcement to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally and to general equitable principles.

SECTION 6.02. No Conflicts; Consents. (a) The execution and delivery of this Agreement by Purchaser does not, and the execution and delivery by Purchaser of each Other Transaction Document to which it is, or is specified to be, a party will not, and the consummation of the transactions contemplated hereby and thereby and compliance with the terms hereof and thereof will not, conflict with, or result in any violation of or default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation or to loss of a material benefit under, or result in the creation of any Lien upon any of the properties, or assets of Purchaser under, any provision of (i) its certificate of incorporation or by-laws, (ii) any Contract to which Purchaser is a party or by which any of its properties or assets are bound or (iii) any

judgment, order, or decree, or, subject to the matters referred to in paragraph (b) below, statute, law, ordinance, rule or regulation applicable to Purchaser on its properties or assets, other than, in the case of clauses (ii) and (iii) above, any such items that, individually or in the aggregate, would not be reasonably likely to have a material adverse effect on the ability of Purchaser to consummate the Acquisition.

(b) No consent, approval, license, permit, order or authorization of or registration, declaration or filing with, any Governmental Entity is required to be obtained or made by or with respect to Purchaser in connection with the execution, delivery and performance of this Agreement, the Other Transaction Documents or the consummation of the transactions contemplated hereby or thereby, other than (i) those that may be required solely by reason of Seller's or any Selling Affiliates' (as opposed to any other third party's) participation in the transactions contemplated hereby or by the Other Transaction Documents and (ii) such consents, approvals, licenses, permits, orders, authorizations, registrations, declarations and filings the absence of which, or the failure to make which, individually or in the aggregate, would not be reasonably likely to have a material adverse effect on the ability of Purchaser to consummate the Acquisition.

SECTION 6.03. Actions and Proceedings. There are no (a) outstanding judgments, orders, injunctions or decrees of any Governmental Entity or arbitration tribunal against Purchaser, (b) lawsuits, actions or proceedings pending or, to the knowledge of Purchaser, threatened against Purchaser, or (c) investigations by any Governmental Entity which are pending or, to the knowledge of Purchaser, threatened against Purchaser, which, in the case of each of clauses (a), (b) and (c), have had or , would be reasonably likely to have a material adverse effect on the ability of Purchaser to consummate the Acquisition.

SECTION 6.04. Availability of Funds. Purchaser has cash available or N has existing borrowing facilities which together are sufficient to enable it to consummate the Acquisition.

SECTION 6.05. No Knowledge of Misrepresentation or Omission. Purchaser has no knowledge that any of the representations and warranties of Seller made in this Agreement or any Other Transaction Document qualified as to materiality are not true and correct, or that those not so qualified are not true and correct in all material ' respects, and Purchaser has no knowledge of any material errors in, or material omissions from, any Section of the Seller Disclosure Schedule.

ARTICLE VII

Covenants of Purchaser

Purchaser covenants and agrees as follows:

SECTION 7.01. Confidentiality. Purchaser acknowledges that the information being provided to it in connection with the

Acquisition and the consummation of the other transactions contemplated hereby and by the Other Transaction Documents (including the terms and conditions of this Agreement and the Other Transaction Documents) is subject to the terms of a confidentiality agreement between Purchaser and Seller dated as of May 9, 2012 (the "Confidentiality Agreement"), the terms of which are incorporated herein by reference. Effective upon, and only upon, the Closing, the confidentiality provisions of the Confidentiality Agreement shall terminate with respect to information relating solely to the Product and the Acquired Assets; *provided, however,* that Purchaser acknowledges that any and all other information provided to it by or on behalf of Seller, any Selling Affiliate or Seller's representatives concerning Seller, the Selling Affiliates or any other Affiliate of Seller and the terms and conditions of this Agreement and the Other Transaction Documents shall remain subject to the terms and conditions of the Confidentiality Agreement after the Closing Date.

SECTION 7.02. No Additional Representations. Purchaser acknowledges that it and its representatives have received or been afforded the opportunity to review prior to the date hereof all written materials which Seller was required to deliver or make.,, available, as the case may be, to Purchaser pursuant to this Agreement on or prior to the date hereof Purchaser acknowledges that it and its representatives have been permitted full and complete access to the books and records, facilities, equipment, Contracts and other properties and assets of Seller and the Selling Affiliates to the extent relating to the Product or the Acquired Assets that it and its representatives have desired or requested to see and/or review, and that it and its representatives have had a full opportunity to meet with the officers and employees of Seller and the Selling Affiliates to discuss the Product, the Acquired Assets and the Assumed Liabilities. Purchaser acknowledges that none of Seller, any Selling Affiliate or any other person has made any representation or warranty: expressed or implied, as to the accuracy or completeness of any information regarding the Acquired Assets or the Assumed Liabilities furnished or made available to Purchaser and its representatives, except as expressly set forth in this Agreement or the Seller Disclosure Schedule, and none of Seller, any Selling Affiliate or any other person shall have or be subject to any liability to Purchaser or any other person resulting from the distribution to Purchaser, or Purchaser's use of, any such information, including the • management presentation material entitled "Project ISIS, Treating and Preventing Infectious Disease" and Project Isis, Supplement to Management Presentation", and any , information, documents or material made available to Purchaser and its representatives in certain virtual or physical "data rooms", visits to physical premises including those of third party manufacturers, or in any other form in expectation of the Acquisition and the other transactions contemplated hereby.

SECTION 7.03. No Use of Certain Names; Transitional License. Purchaser shall promptly, and in any event within ninety (90) days after Closing, (a) revise any and all product literature and labeling to delete all references to the BMS Names and (b) delete all references to Seller's or any Selling Affiliates' customer service address or telephone number. In no event shall Purchaser use any BMS Names, addresses or telephone numbers after the Closing in any manner or for any purpose different from the use of such BMS Names, addresses or telephone numbers by the Seller or any Selling Affiliate with respect to the Product, the Acquired Assets or the conduct of the Business during the 90-day period preceding the Closing. `BMS Names" means "Bristol-Myers", "Bristol-Myers Squibb", "Bristol-Myers Squibb Company", "E.R. Squibb & Sons", "E.R. Squibb", "Westwood", "Westwood-Squibb", "Westwood Squibb Pharmaceuticals Inc.", "Inhibitex, Inc." and "Inhibitex", and any variations and derivatives thereof and any other logos or trademarks of Seller or its Affiliates not included in the Transferred Intellectual Property.

SECTION 7.04. Windfall Profit Sharing. (a) Subject to the rights of Seller under Section 7.04(c), if, at any time prior to the date which is nine (9) months after the Closing Date, Purchaser, directly or indirectly (including through a change of control of Purchaser), (a) sells, transfers, conveys, assigns, licenses, exchanges, leases or otherwise disposes of (including, without limitation, by means of a joint venture or secured financing transaction) (a "Post-Closing Transfer") all or any portion of the Purchased Assets (the "Post-Closing Transferred Assets") or (b) enters into any agreement with any third party which has the effect of a Post-Closing Transfer or which subsequently results in a Post-Closing Transfer, then such Post-Closing Transfer shall be of no force or effect unless and until Purchaser shall have delivered to Seller fifty percent (50%) of (i) the remainder of (A) the Post-Closing Transfer Consideration (including all future milestone and other forms of contingent consideration) *minus* (B) the Purchase Price (or that portion of the Purchase Price attributable to the Post-Closing Transferred Assets based on the purchase price allocation contemplated by Section 8.05(b)) *multiplied by* (ii) the percentage interest in the Post-Closing Transferred Assets transferred in connection with the Post-Closing Transfer (or, in the event of Post-Closing Transfer Consideration (as defined below) not yet then received by Purchaser, evidence of a binding and enforceable agreement pursuant to which Seller will receive such Post-Closing Transfer Consideration from Purchaser upon receipt).

(b) For purposes of this Section 7.04, "Post-Closing Transfer Consideration" shall mean the total consideration received or to be received by Purchaser or by the stockholders or other affiliates of Purchaser in connection with a Post-Closing Transfer..

(c) Notwithstanding anything in this Agreement to the contrary, Purchaser agrees that it shall not consummate any Post-Closing Transfer unless and until the transferee in such transaction assumes in writing (a copy of which must be provided to Seller) the restrictions on and obligations of Purchaser under this Section 7.04.

SECTION 7.05. Advice to Seller. Purchaser shall promptly advise Seller orally and in writing of any change or event occurring between the date of this Agreement and the Closing Date which Purchaser believes would be reasonably likely to have a material adverse effect on the ability of Purchaser to consummate the Acquisition and the other transactions contemplated hereby

SECTION 7.06. Acknowledgement of Assignment. The execution and delivery of this Agreement by Purchaser constitutes an agreement by Purchaser to be bound by the terms and conditions of that certain Patent and Technology License Agreement, dated as of February 2, 2005, between University College Cardiff Consultants Limited and Contravir Research Incorporated (FV-100), as amended March 27, 2007, in accordance with Section 12.1 thereof.

ARTICLE VIII

Mutual Covenants

SECTION 8.01. Consents. Purchaser acknowledges that certain consents and waivers with respect to the transactions contemplated by this Agreement may be ‘ required from parties to the Transferred Contracts and issuers of the Transferred Permits in order to transfer such Transferred Contracts or Transferred Permits to Purchaser and that such consents and waivers have not been obtained. Purchaser agrees that, except for the provision of Section 1.05(b), Seller and its Affiliates shall not have any liability or obligation whatsoever to Purchaser arising out of or relating to the failure to obtain any consents or waivers that may be required in connection with the transactions contemplated by this Agreement or because of the termination of any Transferred Contract or Transferred Permit as a result thereof. Purchaser further agrees that no representation, warranty, covenant or agreement of Seller contained herein shall be breached or deemed breached, and no condition shall be deemed not satisfied, as a result of (a) the failure to obtain any such consent or waiver, (b) any such termination or (c) any lawsuit, action, proceeding or investigation commenced or threatened by or on behalf of any person arising out of or relating to the failure to obtain any such consent or waiver or any such termination. Prior to the Closing, Seller shall, and shall cause the Selling Affiliates to, cooperate with Purchaser, upon the request of Purchaser, in any reasonable manner in connection with Purchaser obtaining any such consents and waivers; *provided, however,* that such cooperation shall not include any requirement of Seller or any of its. Affiliates (including the Selling Affiliates) to expend money, commence, defend or participate in any litigation, incur any obligation in favor of, or offer or grant any accommodation (financial or otherwise) to, any third party.

SECTION 8.02. Cooperation. (a) Purchaser and Seller shall cooperate with each other, and shall cause their respective officers, employees, agents, auditors and representatives to cooperate with each other, for a period of sixty (60) days after the . Closing to ensure the orderly transition of the Product and the Acquired Assets from’ Seller to Purchaser and to minimize any disruption to the respective businesses of Seller, the Selling Affiliates and Purchaser that might result from the transactions contemplated hereby. After the Closing, upon reasonable written notice, Purchaser and Seller shall furnish or cause to be furnished to each other and their employees, counsel, auditors and representatives reasonable access, during normal business hours, to such information and assistance relating to the Product and the Acquired Assets as is reasonably necessary for financial

reporting and accounting matters, the preparation and filing of any Tax returns, reports or forms or the defense of any Tax claim or assessment. The obligation to cooperate pursuant to the preceding sentence insofar as it concerns Taxes shall terminate at the time the relevant applicable statute of limitations expires (giving effect to any extension thereof). Each party shall reimburse the other for reasonable out-of-pocket costs and expenses incurred in assisting the other pursuant to this Section 8.02. Neither =. party shall be required by this Section 8.02 to take any action that would unreasonably interfere with the conduct of its business or unreasonably disrupt its normal operations.

(b) From time to time, as and when requested by either party hereto, the other party shall execute and deliver, or cause to be executed and delivered, all such documents and instruments and shall take, or cause to be taken, all such further or other actions (subject to the provisions of Sections 8.01 and 8.05), as such other party may reasonably deem necessary or desirable to consummate the transactions contemplated by this Agreement.

SECTION 8.03. Publicity. Seller and Purchaser agree that no public release or announcement concerning the transactions contemplated hereby shall be issued by either party or its Affiliates without the prior written consent of the other party (which consent shall not be unreasonably withheld), except as such release or announcement’ may be required by Applicable Law or the rules or regulations of any United States or foreign securities exchange to which such party is subject, in which case the party required to make the release or announcement shall allow the other party reasonable time to comment on such release or announcement in advance of such issuance.

SECTION 8.04. Bulk Transfer Laws. Purchaser hereby waives compliance by Seller and its Affiliates with the provisions of any so-called “bulk transfer law” of any jurisdiction in connection with the sale of the Acquired Assets to Purchaser.

SECTION 8.05. Transfer Taxes; Purchase Price Allocation; Entitlement to Tax Refunds and Credits; Proration of Non-Income Taxes.

(a) All Transfer Taxes and any filing or recording fees applicable to the Acquisition shall be paid by Purchaser. Each party shall use reasonable efforts to avail itself of any available exemptions from any such Taxes or fees, and to cooperate with the other party in providing any information and documentation that may be necessary to obtain such exemptions.

(b) Seller shall allocate the Purchase Price among the Acquired Assets, subject to Purchaser's consent, such consent not to be unreasonably withheld. Such allocation will comply with the requirements of Section 1060 of the Code. Each of Seller and Purchaser agrees that it shall (i) report the sale and purchase of the Acquired Assets for United States Tax purposes in accordance with such allocations and (ii) not take any position inconsistent with such allocations on any of their respective United States Tax Returns.

(c) Seller shall be entitled to any refunds or credits of Taxes relating to any Excluded Tax Liability. Purchaser shall be entitled to any refunds or credits of Taxes relating to the Acquired Assets, other than any such refunds or credits of Taxes relating to any Excluded Tax Liability.

(d) Any value-added, goods and services, stamp duties, ad valorem and similar Taxes shall be allocated between portions of a tax period that includes (but does not end on) the Closing Date (a "Straddle Period") in the following manner: (i) in the' case of a Tax imposed in respect of property and that applies ratably to a Straddle Period, the amount of Tax allocable to a portion of the Straddle Period shall be the total amount of such Tax for the period in question multiplied by a fraction, the numerator of which is, the total number of days in such portion of such Straddle Period and the denominator of which is the total number of days in such Straddle Period, and (ii) in the case of sales, value added and similar transaction-based Taxes (other than Transfer Taxes), such Taxes shall be allocated to the portion of the Straddle Period in which the relevant transaction. occurred.

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

SECTION 8.06. Recordation of Transfer of Intellectual Property. Purchaser shall be responsible, at its sole cost and expense, for all applicable recordations of the assignment of the Transferred Intellectual Property.

SECTION 8.07. Retention of Certain Records. Seller may retain all Records prepared in connection with the transactions contemplated by this Agreement, including bids received from other parties and analyses relating to the Product and such Records shall be Excluded Records for all purposes hereunder.

ARTICLE IX

Indemnification

SECTION 9.01. Indemnification by Seller. From and after the Closing, Seller shall indemnify Purchaser and its Affiliates and each of their respective officers, directors, employees, agents and representatives against and hold them harmless from any loss, liability, claim, damage or expense (including reasonable legal fees and expenses) ("Losses") suffered or incurred by any such indemnified party to the extent arising from (i) any breach of any representation or warranty of Seller contained in Sections 4.01, 4.02, 4.04 or 4.05 of this Agreement which survives the Closing, and (ii) any breach of any covenant of Seller contained in this Agreement requiring performance after the Closing Date. Notwithstanding the forgoing, (a) Seller shall not have any liability under clause (i) of this Section 9.01 unless the aggregate of all Losses for which Seller would be liable, but for this clause (a), exceeds on a cumulative basis an amount equal to $50,000.00, and then only to the extent of any such excess; (b) Seller shall not have any liability under clause (i) of this Section 9.01 for any individual item (or series of related items) where the Loss relating thereto is less than $10,000.00 and such` items shall not be aggregated for purposes of the foregoing clause (a) of this Section 9.01; (c) Seller shall not have any liability under clause (i) of this Section 9.01 for any breach of a representation or warranty if Purchaser had knowledge of such breach at the time of the Closing and such breach would have given rise to a failure to be satisfied of the condition to Purchaser's obligations set forth in Section 3.01(a); (d) Seller's liability under clause (i) of this Section 9.01 shall in no event exceed ten percent (10%) of the Base Purchase Price; and (e) Seller shall not have any liability under this Section 9.01 to the extent the liability or obligation arises as a result of (x) any action taken or omitted to be taken by Purchaser or any of its Affiliates or (y) any breach of a representation or warranty that is covered by a certificate delivered pursuant to Section 3.02(a) except to the extent Seller had knowledge that such representation or warranty was not true and correct in all material respects when made.

SECTION 9.02. Indemnification by Purchaser. From and after the Closing, Purchaser shall indemnify Seller and its Affiliates and each of their respective officers, directors, employees, agents and representatives against and hold them harmless from any Loss suffered or incurred by any such indemnified party to the extent arising from (i) any breach of any representation or warranty of Purchaser which survives the Closing contained in this Agreement, (ii) any breach of any covenant of Purchaser contained in this Agreement requiring performance after the Closing Date and (iii) any Assumed Liability.

SECTION 9.03. Limitations on Liability: Cooperation. (a) Notwithstanding any provision herein, neither Seller nor Purchaser shall in any event be liable to the other party or its Affiliates, officers, directors, employees, agents or representatives on account of any indemnity obligation set forth in Section 9.01 or Section 9.02 for any indirect, consequential, special, incidental or punitive damages (including lost profits, loss of use, damage to goodwill or loss of business).

(b) Purchaser and Seller shall cooperate with each other with respect to resolving any claim or liability with respect to which one party is obligated to indemnify the other party hereunder including by making commercially reasonable efforts to mitigate or resolve any such claim or liability.

(c) Purchaser acknowledges and agrees that, (i) other than the representations and warranties of Seller specifically contained in this Agreement, there are no representations or warranties of Seller, any Selling Affiliate or any other person either expressed or implied with respect to the Acquisition or the other transactions contemplated hereby, the Product, the Acquired Assets or the Assumed Liabilities and (ii) it shall have no claim or right to indemnification pursuant to Section 9.01 with respect to any information, documents or materials (other than this Agreement and the Seller Disclosure Schedule) furnished by Seller, any Selling Affiliate or any of their respective officers, directors, employees, agents or advisors to Purchaser and its representatives, including the management presentation material entitled "Project ISIS, Treating and Preventing Infectious Disease" and Project Isis, Supplement to Management Presentation", and any information, documents or material made available to Purchaser and its representatives in certain virtual or physical "data rooms", visits to physical premises including those of third party manufacturers, or in any other form in expectation of the transactions contemplated hereby.

(d) Purchaser further acknowledges and agrees that, should the Closing occur, its sole and exclusive remedy with respect to any and all claims relating to this Agreement, any Other Transaction Document, the Acquisition, any document or certificate delivered in connection herewith, the Product, the Acquired Assets and the Assumed Liabilities or any Federal, state, local or foreign statute, law, ordinance, rule or regulation or otherwise (other than claims of, or causes of action arising from, fraud) shall be pursuant to the indemnification provisions set forth in this Article IX. In furtherance of the foregoing, Purchaser hereby waives, from and after the Closing, to the fullest extent permitted under Applicable Law, any and all rights, claims and causes Of action (other than claims of, or causes of action arising from, fraud) it or any of its Affiliates may have against Seller and its Affiliates arising under or based upon this Agreement, any Other Transaction Document, the Acquisition, any document or certificate delivered in connection herewith, the Product, the Acquired Assets and the Assumed Liabilities or any Federal, state, local or foreign statute, law, ordinance, rule or regulation or otherwise (except pursuant to the indemnification provisions set forth in this Article IX).

SECTION 9.04. Losses Net of Insurance, etc. The amount of any Loss for which indemnification is provided under this Article IX shall be net of any amounts recovered or recoverable by the indemnified party under insurance policies with respect to such Loss and shall be reduced to take account of any net Tax benefit (including as a result of any basis adjustment) actually realized by the indemnified party arising from the incurrence or payment of any such Loss. In computing the amount of any such Tax benefit, the indemnified party shall be deemed to recognize all other items of income, gain, loss, deduction or credit before recognizing any item arising from the incurrence or payment of any indemnified Loss.

SECTION 9.05. Termination of Indemnification. (a) The obligations to indemnify and hold harmless a party hereto pursuant to (i) Sections 9.01(i) and 9.020), shall terminate when the applicable representation or warranty terminates pursuant to paragraph (b) below and (ii) the other clauses of Sections 9.01 and 9.02 shall not terminate; *provided, however,* that as to clause (i) of this sentence such obligations to indemnify and hold harmless shall not terminate with respect to any item as to which the person to be indemnified or the related party thereto shall have, before the expiration of the applicable period, previously made a claim by delivering a notice of such claim (stating in reasonable detail the basis of such claim) to the indemnifying party.

(b) The representations and warranties in this Agreement shall survive the Closing solely for purposes of Sections 9.01 and 9.02 and shall terminate at the close of business on the first year anniversary of the Closing Date.

SECTION 9.06. Procedures Relating to Indemnification for Third Party Claims. (a) In order for a party (the "indemnified party") to be entitled to any indemnification provided for under this Agreement in respect of, arising out of or involving a claim or demand made by any person against the indemnified party (a "Third Party Claim"), such indemnified party must notify the indemnifying party in writing, and in reasonable detail, of the Third Party Claim within ten (10) business days after receipt by such indemnified party of written notice of the Third Party Claim; *provided, however,* that failure to give such notification shall not affect the indemnification provided hereunder except to the extent the indemnifying party shall have been prejudiced as a result of such failure (except that the indemnifying party shall not be liable for any expenses incurred during the period in which the indemnified party failed to give such notice). Thereafter, the indemnified party shall deliver to the indemnifying party, promptly after the indemnified party's receipt thereof, copies of all notices and documents (including court papers) received by the indemnified party relating to the Third Party Claim.

(b) If a Third Party Claim is made against an indemnified party, the indemnifying party shall be entitled to participate in the defense thereof and, if it so chooses, to assume the defense thereof with counsel selected by the indemnifying party; *provided, however,* that such counsel is not reasonably objected to by the indemnified party. Should the indemnifying party so elect to assume the defense of a Third Party Claim, the indemnifying party shall not be liable to the indemnified party for legal expenses subsequently incurred by the indemnified party in connection with the defense thereof. If the indemnifying party assumes such defense, the indemnified party shall have the right to participate in the defense thereof and to employ counsel (not reasonably objected to by the indemnifying party), at its own expense, separate from the counsel employed by the indemnifying party, it being understood that the indemnifying party shall control such defense. The indemnifying party shall be liable for the fees and expenses of counsel employed by the indemnified party for any period during which the indemnifying party has failed to assume the defense thereof (other than during the period prior to the time the indemnified party shall have given notice of the Third Party Claim as provided above).

(c) If the indemnifying party so elects to assume the defense of any Third Party Claim, all of the indemnified parties shall cooperate with the indemnifying party in the defense or prosecution thereof. Such cooperation shall include the retention and (upon the indemnifying party's request) the provision to the indemnifying party of records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. Whether or not the indemnifying party shall have assumed the defense of a Third Party Claim, the indemnified party shall not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the indemnifying party's prior written consent (which consent shall not be unreasonably withheld).

SECTION 9.07. Procedures Related to Indemnification for Other Claims. In the event any indemnified party should have a claim against any indemnifying party under Section 9.01 or 9.02 that does not involve a Third Party Claim being asserted against or sought to be collected from such indemnified party, the indemnified party shall deliver notice of such claim with reasonable promptness to the indemnifying party. The failure by any indemnified party to so notify the indemnifying party shall not relieve the indemnifying party from any liability which it may have to such indemnified party under Section 9.01 or 9.02, except to the extent that the indemnifying party demonstrates that it has been materially prejudiced by such failure. If the indemnifying party disputes its liability with respect to such claim, the indemnifying party and the indemnified party, shall proceed in good faith to negotiate a resolution of such dispute and, if not resolved through negotiations, such dispute shall be resolved by litigation in an appropriate court of competent jurisdiction.

SECTION 9.08. Tax Treatment of Indemnification Payments. For all Tax purposes, Purchaser, Seller and each of their respective Affiliates agree to treat any indemnity payment under this Agreement as an adjustment to the Purchase Price received by the Seller for the transactions contemplated by this Agreement unless a final determination (as defined in Section 1313 of the Code) provides otherwise.

ARTICLE X

Termination

SECTION 10.01. Termination. This Agreement may be terminated and the transactions contemplated hereby abandoned at any time prior to the Closing by:

(a) mutual written consent of Seller and Purchaser;

(b) Seller if any of the conditions set forth in Section 3.02 shall have become incapable of fulfillment, and shall not have been waived by Seller;

(c) Purchaser if any of the conditions set forth in Section 3.01 shall have become incapable of fulfillment, and shall not have been waived by Purchaser; or

(d) either party hereto, if the Closing does not occur on or prior to August 31, 2012;

(e) Purchaser or Seller in the event of the institution against the other party of any proceeding under the United States Bankruptcy Code or any other federal or, state bankruptcy, reorganization, receivership, insolvency or other similar Law affecting the rights of creditors generally, which proceeding is not dismissed within thirty (30) days of filing, or the institution by the other party of any proceeding under the United States Bankruptcy Code or any other federal or state bankruptcy, reorganization, receivership, insolvency or other similar Law affecting the rights of creditors generally or the making by the other party of a composition or an assignment or trust mortgage f6r the benefit of creditors;

provided, however, that the party seeking termination pursuant to clause (b), (c) or (d) is not in breach in any material respect of any of its representations, warranties, covenants or agreements contained in this Agreement.

SECTION 10.02. Return of Confidential Information. If the transactions contemplated by this Agreement are terminated as provided herein:

(a) Purchaser shall return to Seller all documents and other material received by Purchaser, its Affiliates and their respective representatives from Seller, any Selling Affiliate or any of their respective Affiliates or representatives relating to the transactions contemplated hereby and by the Other Transaction Documents, whether so, obtained before or after the execution hereof; and

(b) all confidential information received by Purchaser, its Affiliates and their respective representatives with respect to Seller, any Selling Affiliate or any of their respective Affiliates, the Product and the Acquired Assets shall be treated in accordance with the Confidentiality Agreement, which shall remain in full force and effect notwithstanding the termination of this Agreement.

SECTION 10.03. Consequences of Termination. In the event of termination of this Agreement by Seller or Purchaser pursuant to this Article X, written notice thereof shall forthwith be given to the other party and the transactions contemplated by this Agreement shall be terminated, without further action by either party. If this Agreement is terminated and the transactions contemplated hereby are abandoned as described in this Article X, this Agreement shall become void and of no further force or effect, except for the provisions of (a) Section 7.01 relating to the obligation of Purchaser to keep confidential certain information and data obtained by it, (b) Section 11.03 relating to certain expenses, (c) Section 11.04 relating to attorney fees and expenses, (d) Section 8.03 relating to publicity, (e) Section 11.10 relating to finder's fees and broker's fees and (f) this Article X. Nothing in this Article X shall be deemed to release either party from any liability for any intentional and material breach by such party of the terms and provisions of this Agreement prior to such termination or to

impair the right of either party to compel specific performance by the other party of its obligations under this Agreement.

ARTICLE XI

Miscellaneous

SECTION 11.01. Assignment. This Agreement and the rights and obligations hereunder shall not be assignable or transferable by Purchaser or Seller (including by operation of law in connection with a merger, consolidation or sale of substantially all the assets of Purchaser or Seller) without the prior written consent of the other party hereto; *provided,* that Seller may assign its rights and obligations hereunder (a) to any direct or indirect wholly owned subsidiary of Seller or (b) to any transferee of all or substantially all of the assets of Seller, and *provided, further,* that, subject to Purchaser's obligations under Section 7.04, Purchaser may assign its rights and obligations hereunder to any transferee of all or substantially all of the assets of Purchaser that relate to the Product pursuant to a merger, consolidation or otherwise, to the extent that the transferee assumes in writing all of the obligations of Purchaser that relate to the Product under this Agreement, in either case without the consent of Purchaser. Any attempted assignment in violation of this Section 11.01 shall be void.

SECTION 11.02. No Third-Party Beneficiaries. Except as provided in Article X, this Agreement is for the sole benefit of the parties hereto and their permitted assigns and nothing herein expressed or implied shall give or be construed to give to any person, other than the parties hereto and such assigns, any legal or equitable rights hereunder.

SECTION 11.03. Expenses. Whether or not the transactions contemplated hereby are consummated, and except as otherwise specifically provided in this Agreement, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the party incurring such costs or expenses.

SECTION 11.04. Attorney Fees. A party in breach of this Agreement shall, on demand, indemnify and hold harmless the other party for and against all reasonable out-of-pocket expenses, including legal fees, incurred by such other party by reason of the enforcement and protection of its rights under this Agreement. The payment of such expenses is in addition to any other relief to which such other party may be entitled.

SECTION 11.05. Amendments. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the parties hereto. By an instrument in writing Purchaser, on the one hand, or Seller, on the other hand, may waive compliance by the other with any term or provision of this Agreement that such other party was or is obligated to comply with or perform.

SECTION 11.06. Notices. All notices or other communications required' or permitted to be given hereunder shall be in writing and shall be delivered by hand or sent by prepaid telex, cable or telecopy or sent, postage prepaid, by registered, certified or express mail or reputable overnight courier service and shall be deemed given when so delivered by hand, telexed, cabled or telecopied, or if mailed, three days after mailing (one business day in the case of overnight mail or overnight courier service), as follows:

(a) if to Purchaser,

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

Telefax: (212) 297-0019
Attention: Gary Jacob

with a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
666 Third Avenue
New York, New York 10017
Telephone: (212) 935-3000
Telefax: (212) 983-3115
Attention: Ivor Elrifi, Esq.

(b) if to Seller,

Bristol-Myers Squibb Company
345 Park Avenue
New York, New York 10154-0037
Attention: General Counsel

with a copy to:

Bristol-Myers Squibb Pharmaceutical Group
Route 206 & Province Line Road
Princeton, New Jersey 08540
Attention: Vice President and Associate General Counsel,
Transactional Practice Group

SECTION 11.07. Interpretation; Exhibits, Seller Disclosure Schedule and Other Schedules; Certain Definitions. (a) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such. amendments, supplements or modifications set forth therein), (ii) the words “herein”,. “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (iii) all references herein to Articles, Sections, Appendices, Exhibits or Schedules shall be construed to refer to Articles, Sections, Appendices, Exhibits and Schedules of this Agreement and (iv) the headings contained in this Agreement, the Seller Disclosure Schedule, other Schedules or any Appendix or Exhibit and in the table of contents to this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Any matter set forth in any provision, subprovision, section or subsection of the Seller Disclosure Schedule shall be deemed set forth for all purposes of the Seller” Disclosure Schedule to the extent relevant and reasonably apparent. The Seller Disclosure Schedule, all other Schedules and all Appendices and Exhibits annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in MI herein. Any capitalized terms used in the Seller Disclosure Schedule, any other Schedule or any Appendix or Exhibit annexed hereto but not otherwise defined therein, shall have the meaning as defined in this Agreement. In the event of an ambiguity or a question of intent or interpretation, this Agreement shall be construed as if drafted jointly by the parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

(b) For all purposes hereof:

“Accounts Payable” means all accounts payable and liabilities, obligations and commitments, regardless of when asserted, billed or imposed, of Seller or the Selling Affiliates as of the end of the day immediately prior to the Closing Date.

“Accounts Receivable” means all accounts receivable, notes receivable and other indebtedness due and owed by any third party to Seller or the Selling Affiliates as of the end of the day immediately prior to the Closing Date, including all trade accounts receivable representing amounts receivable in respect of goods shipped, products sold or services rendered prior to the day immediately prior to the Closing Date and the full benefit of any security for such accounts or debts.

“Affiliate” means, with respect to any specified person, any other person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified person; and for the purposes of this definition, “control” when used with respect to any specified person means the power to direct the management and policies of such person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise; and the terms “controlling” and “controlled” have ‘ meanings correlative to the foregoing.

“Assumption Agreement” means the assumption agreement to be executed by Purchaser to evidence its assumption of the Assumed Liabilities.

“Bill of Sale” means a bill of sale and assignment with respect to the Acquired Assets.

"BLA" means a Biologic License Application, as defined in the United States Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder.

"BMS Prior Manufacturing Costs" means $400,000.00 of manufacturing costs to which the Seller has committed for the month of June, 2012.

"business day" means any day, other than a Saturday or Sunday, on which commercial banks are not required or authorized to close in the City of New York.

"Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending March 31, June 30, September 30 and December 31.

"Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31.

"Commencement of a Phase lib Clinical Trial" means the first dosing of the Product in a human patient in a Phase II Clinical Trial, designed to support and immediately precede the initiation of a Phase III Clinical Trial program without any , further Phase II Clinical Trials, to evaluate the dose-dependent effectiveness of a pharmaceutical product for a particular indication or indications in patients with the disease or condition under study and to determine the common side effects and risks associated with the pharmaceutical product. For purposes of this Agreement, in cases where a Phase IIb/III Clinical Trial precedes any Phase IIb Clinical Trial for the Product, the first dosing of the Product in a human patient in a Phase IIb/III Clinical Trial shall be deemed to be the "Commencement of a Phase IIb Clinical Trial" for the Product.

"Commencement of a Phase III Clinical Trial" means the first dosing of the Product in a human patient in human clinical trial of the Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions and

adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which trial is intended to support Approval of the Product, as described in 21 C.F.R. 312.21(c) for the United States, or a similar clinical study prescribed by the applicable Governmental Entity in a foreign country. For purposes of this Agreement, in the case where a Phase IIb/III Clinical Trial precedes any Phase III Clinical Trial for the Product, the first dosing of the Product in a human patient following the review of interim data and decision to extend the period of such Phase IIb/III Clinical Trial in order to provide sufficient evidence of safety and efficacy to be included as a Phase III Clinical Trial in filings with the applicable Governmental Entity shall be deemed to be the "Commencement of a Phase III Clinical Trial" for the Product.

"commercially reasonable and diligent efforts" means that level of effort which, consistent with the exercise of prudent scientific and business judgment, is applied by Purchaser to its other therapeutic products at a similar stage of development and With similar commercial potential.

"Dollars" or "$" means lawful money of the United States of America.

"Environmental Law" means any notice of liability, inquiry or violation, Law or Injunction issued by or entered into with any Governmental Entity, relating to pollution, protection of the environment or human health or the preservation or restoration of natural resources.

"Environmental Liability" means any Liability, loss, demand, claim or cost, contingent or otherwise (including any Liability for judgments, orders, damages, costs of investigation, remediation or monitoring, medical monitoring, natural resources damages, fines, penalties, professional fees, or settlements), and relating to, arising under or resulting from (a) any actual or alleged (i) compliance or noncompliance with any Environmental Law or Environmental Permit, (ii) generation, use, storage, management, treatment, transportation or disposal of any Hazardous Material or (iii) presence, Release or threatened Release of, or exposure to, any Hazardous Material (including any exposure of any Business Employee, Former Business Employee, Transferred Employee or foriner employee or independent contractor of the Transferred Entities or the Business to Hazardous Materials) or (b) any contract, agreement, or other consensual arrangement pursuant to which liability is assumed or imposed with respect to any of the foregoing.

"Environmental Permit" means any certificate, consent, permit, license, registration, approval or other authorization issued under or pursuant to Environmental Laws or otherwise relating to the use, emission or discharge of Hazardous Materials.

"First Commercial Sale" means, with respect to the Product, the first sale for use or consumption by the general public of the Product in any country in the Territory after Approval of the Product has been granted, or such marketing and sale is otherwise permitted, by the applicable Governmental Entity of such country.

"GAAP" means generally accepted accounting principles in the United States.

“Hazardous Material” means any hazardous, toxic or deleterious chemical, material, substance or waste, including radioactive, explosive, medical or biohazardous materials or wastes, petroleum and its byproducts and distillates, asbestos or asbestos-containing materials, polychlorinated biphenyls, radon gas, or urea formaldehyde foam insulation.

“including” means including, without limitation.

“IP Assignment Documents” means with respect to any Transferred Intellectual Property, intellectual property (patent, trademark, copyright and domain name assignments, as applicable) assignments of such Transferred Intellectual Property.

“knowledge of Seller” means the current actual knowledge of (i) Maureen Gibbons, Senior Corporate Counsel, Intellectual Property — Patents, of Seller, (ii) Brian Heaphy, Director, Strategic Transactions, of Seller, and (iii) Joseph M. Patti, General Manager, Chief Scientific Officer, and Senior Vice President, Research & Development, Inhibitex, Inc.

“Manufacturing Knowhow” means knowhow, technology, data, designs, process and methods relating to the manufacture and production of products.

“Marketing Approval” means, with respect to any Product in any regulatory jurisdiction, approval from the applicable Governmental Entity sufficient.for the manufacture, distribution, use and sale of the Product in such jurisdiction in accordance with applicable Laws.

“Material Adverse Effect” means any change, effect, event or occurrence or state of facts that individually or taken together with other changes, effects, events or occurrences or state of facts, (i) is, or would reasonably be expected to be, materially adverse to the Business, the Product and the Acquired Assets, taken as a whole or (ii) would prevent or materially impede, interfere with, hinder or delay the consummation by Seller of transactions contemplated by this Agreement, other than, with respect to any’ change, effect, event or occurrence or state of facts having the results described in the foregoing clause (i), any change, effect, event or occurrence or state of facts relating to (A) economic, financial market or geographical conditions in general (including national or international conditions), (B) changes in Applicable Law or GAAP or other applicable accounting regulations or principles or interpretations thereof, (C) changes in conditions generally affecting the pharmaceutical or biotechnology industries, (D) the announcement of this Agreement and the transactions contemplated hereby and performance of and compliance with the terms of this Agreement, (E) any acts or omissions of Seller or any of its Affiliates taken after the date of this Agreement with the prior written consent of Purchaser pursuant to Section 5.02, (F) any changes in global or national political conditions, (G) any outbreak or escalation of hostilities, any occurrence or threat of acts commonly referred to as terrorist attacks or any armed hostilities associated therewith and any national or international calamity or emergency or any escalation thereof or (H) any of the matters described in Section 4.11 of the Seller Disclosure Schedule.

“NDA” means a new drug application for a drug filed in accordance with 21 C.F.R. Part 314, and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning the applicable drug which are necessary for FDA approval to market such drug in the United States, and any equivalent application submitted to any other health authority.

“Net Sales” means, with respect to the Product, the amount billed by Purchaser or an Affiliate of Purchaser for sales of Product in arm’s length transactions to Third Parties, after deduction (if not already deducted in the amount invoiced) of the following items with respect to sales of the Product:

(a) trade, cash, and/or quantity discounts, charge-back payments and rebates actually taken and allowed (including, without limitation, cash discounts and quantity discounts), charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers, including but not limited to wholesalers, chains and pharmacy buying groups (a “Discount”);. *provided however,* that where any such Discount is based on sales of a bundled set of products in which the Product is included, and in which the individual Discount for the Product is not itemized or otherwise determinable, the Discount shall be allocated to the Product on *a pro rata* basis based on the sales value (i.e., the unit average selling price multiplied by the

unit volume) of the Product relative to the sales value contributed by the other constituent products in the relevant bundled set, with respect to such sale;

(b) credits or allowances given or recorded for rejection or return of • previously sold Product (including, without limitation, returns of the Product in connection with recalls or withdrawals);

(c) any tax, tariff, duty, surcharges or government charge (including any tax such as a value added or similar tax or government charge other than an income tax) levied on the exportation, sale, transportation or delivery of the Product to the extent not paid by a Third Party;

(d) freight out, postage, shipping and insurance charges for delivery of the Product if separately set out on the invoice; and

(e) amounts written off by reason of uncollectible debt

Net Sales and all of the foregoing deductions from the gross invoiced sales prices of the Product shall be determined in accordance with Purchaser's standard accounting procedures and in accordance with GAAP in each case consistently applied. In the event Purchaser or its Affiliates make any adjustments to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments shall be reported and reconciled with the next report and payment of any royalties due under Article 5. The Product shall be considered "sold" when it is invoiced, shipped or paid for, whichever shall occur first.

Net Sales shall not include any payments among a Party, its Affiliates and Sublicensees. For sake of clarity and avoidance of doubt, sales by Purchaser, its Affiliates or Sublicensees of the Product to a Third Party distributor or wholesaler shall be considered a sale to a Third Party customer.

"Other Transaction Documents" means (i) the Bill of Sale, (ii) the Assumption Agreement and (iii) the IP Assignment Documents.

"person" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, Governmental Entity or other entity.

"Phase II Clinical Trial" means a human clinical trial of the Product, the principal purpose of which is a determination of preliminary short-term safety and efficacy in the target patient population, as described in 21 C.F.R. 312.21(b) for the United States, or a similar clinical study prescribed by the applicable Governmental Entity in a foreign country.

"Phase IIb/III Clinical Trial" means a human clinical trial of a compound or product, the principal purpose of which is a further determination of efficacy and safety, in the target population, at the intended clinical dose or ranges of doses, on a sufficient number of subjects and for a sufficient period of time to confirm the optimal manner of use of the Product (dose and dose regimen) prior to the initiation of the pivotal Phase III Trials, and which itself provides sufficient evidence of safety and efficacy to be included as a Phase III Trial in filings with Governmental Entities.

"Prime Rate" means the rate of interest from time to time publicly announced by Citibank, N.A. in its New York City office as its prime or base rate, calculated on the basis of the actual number of days elapsed over three hundred sixty five (365).

"Product Formulae" means the specific percentages and specifications for the mixing and preparation of the ingredients used in the manufacture of the Product, taken as a whole and not in part. For the avoidance of doubt, (a) the Product Formulae does not include Manufacturing Knowhow associated with the manufacture of the Product to which such Product Formulae relates and (b) does not refer separately to a particular ingredient or specification or combination of ingredients and/or specifications that do not comprise the entire, specific Product Formulae.

"Regulatory Filing" means the acceptance by the FDA of the filing of a BLA or an NDA for the Product, the filing with the European Agency for the Evaluation of Medicinal Product, or any successor agency thereto (the "EMEA"), of a marketing authorization application ("MAA") for the Product under the centralized European procedure or if the centralized EMEA filing procedure is not used, a filing of the MAA for the Product in any European country, or any similar filing in any other country as prescribed by the applicable Governmental Entity in such country.

"Selling Affiliate" means each Affiliate of the Seller identified in Section 1(a)(i) of the Seller Disclosure Schedule.

"Sublicensee" means any person to whom or which the Product is licensed from Purchaser.

"subsidiary" of any person means another person, an amount of the voting securities, other voting ownership or voting partnership interests of which is sufficient to elect at least a majority of its Board of Directors or other governing body (or, if there are no such voting interests, fifty percent (50%) or more of the equity interests of which) is owned directly or indirectly by such first person or by another subsidiary of such person.

"United States" means the United States of America, including its territories and possessions (excluding all military bases and other military installations outside of the continental United States, Alaska, Hawaii and Washington, D.C.).

"Valid Claim" means a claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue).

(f) The following terms have the meanings given such terms in the Sections set forth below:

Term	Section
Accounting Firm	2.02(b)
Accounts Payable	11.07(b)
Accounts Receivable	11.07(b)
Acquired Assets	1.05(a)
Acquisition	1.01
Affiliate	11.07(b)
Applicable Laws	4.09
Assumed Liabilities	1.06(a)
Base Purchase Price	1.01
Benefit Plan	4.12(a)
BMS Names	7.03

Term	Section
business day	11.07(b)
Calendar Quarter	11.07(b)
Calendar Year	11.07(b)
Closing	2.01
Closing Date	2.01
Code	4.03(a)
Commencement of a Phase IIb Clinical Trial	11.07(b)
Commencement of a Phase III Clinical Trial	11.07(b)
commercially reasonable and diligent efforts	11.07(b)
Confidentiality Agreement	7.01
Contracts	1.05(a)(iii)
Control	11.07(b)
Determination Period	1.02(d)
DOJ	8.05
Dollars	11.07(b)
Employee Benefit Plan	4.12(a)
Environmental Law	11.07(b)
Environmental Liabilities	11.07(b)
Environmental Permit	11.07(b)
Excluded Assets	1.05(b)
Excluded Contracts	1.05(b)(vi)
Excluded Environmental Permits	1.05(b)(vii)
Excluded Intellectual Property	1.05(b)(iii)
Excluded Inventory	1.05(b)(iv)
Excluded Liabilities	1.06(b)
Excluded Miscellaneous Rights	1.05(b)(v)
Excluded Permits	1.05(b)(vii)
Excluded Records	1.05(b)(viii)
Excluded Tax Liability	1.06(b)(ii)
FDA	7.04
GAAP	11.07(b)
Governmental Entity	3.0 1 b
Hazardous Material	11.07(b)
including	11.07(a)
indemnified part	9.06
Knowledge of Seller	11.07(b)
Liabilities	1.03(a)
Liens	4.02(a)
Losses	9.01
Manufacturing Knowhow	11.07(b)
Marketing Approval	11.07(b)
Material Adverse Effect	11.07(b)
Milestone Event	1.02(a)
Milestone Payment	1.02(a)

NDA	11.07(b)

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

Term	**Section**
Net Sales	11.07(b)
Notice of Disagreement	2.02(b)
Other Transaction Documents	11.07(b)
Permits	1.05(a)(iv)
Permitted Liens	4.04
Person	11.07(b)
Personal Property	1.05(a)(viii)
Phase II Clinical Trial	11.07(b)
Phase IIMII Clinical Trial	11.07(b)
Post-Closing Tax Period	4.03(a)
Pre-Closing Tax Period	4.03(a)
Prime Rate	11.07(b)
Product Formulae	11.07(b)
Product Patent Rights	1.03(c)
Product	1.02(a)
Purchase Price	1.01
Purchaser	Preamble
Records	1.05(a)(v)
Regulatory Filing	11.07(b)
Royalty Payment	1.03
Royalty Term	1.03(c)
Term	Section
Scientific Expert	1.02(d)
Selected Scientific Expert	1.02(d)
Seller	Preamble
Seller Disclosure Schedule	Article IV
Selling Affiliate	11.07(b)
Statement	2.02(a)
Straddle Period	8.06(d)
Sublicensee	11.07(b)
Tax	4.03(a)
Taxes	4.03(a)
Technology	1.05(a)(i)(D)
Third Party Claim	9.06
Transfer Taxes	1.06(a)(v) .
Transferred Contracts	1.05(a)(iii)
Transferred Environmental Permits	1.05(a)(v)
Transferred Intellectual Property	l.05(a)(i)
Transferred Invento	.05(a)(ii) (1)
Transferred Patents	1.05(a)(i)(A)
Transferred Permits	1.05(a)(iv)
Transferred Personal Property	.05(a)(viii) (1)
Transferred Records	1.05(a)(vi)
United States	11.07(b)
Valid Claims	11.07(b)

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

SECTION 11.08. Counterparts. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement, and shall become effective when one or more such counterparts have been signed by each of the parties and delivered to the other party.

SECTION 11.09. Entire Agreement. This Agreement, the Technology License Agreement and the Confidentiality Agreement contain the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersede all prior agreements and understandings relating to such subject matter. Neither party shall be liable or bound to any other party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth herein, in the Technology License Agreement or in the Confidentiality Agreement.

SECTION 11.10. Fees. Purchaser hereto hereby represents and warrants that no brokers or finders that have acted for Purchaser in connection with this Agreement or the transactions contemplated hereby or that may be entitled to any brokerage fee, finder's fee or commission in respect thereof.

SECTION 11.11. Severability. If any provision of this Agreement (or any portion thereof) or the application of any such provision (or any portion thereof) to. any person or circumstance shall be held invalid, illegal or unenforceable in any respect by a court of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision hereof (or the remaining portion thereof) or the application of such provision to any other persons or circumstances.

SECTION 11.12. Consent to Jurisdiction. Each of Purchaser and Seller irrevocably submits to the exclusive jurisdiction of (a) the Supreme Court of the State of New York, New York County, and (b) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement, the Technology License Agreement or any transaction contemplated hereby or thereby. Each of Purchaser and Seller agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, New York County. Each of Purchaser and Seller further agrees that service of any process, summons, notice or document by U.S. registered mail to such party's respective address(es) set forth above shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 12.12. Each of Purchaser and Seller irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement, the Technology License Agreement or the transactions contemplated hereby or thereby in (i) the Supreme Court of the State of New York, New York County, or (ii) the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 11.13. Waiver of Jury Trial. Each party hereto hereby waives to the fullest extent permitted by Applicable Law, any right it may have to a trial by jury in respect of any litigation directly or indirectly arising out of, under or in connection with this Agreement, the Technology License Agreement or any transaction contemplated hereby or thereby. Each party hereto (a) certifies that no representative, \ agent or attorney of any other party has represented, expressly or otherwise, that such other party would not, in the event of litigation, seek to enforce that foregoing waiver and (b) acknowledges that it and the other parties hereto have been induced to enter into this Agreement and the Technology License Agreement, as applicable, by, among other things, the mutual waivers and certifications in this Section 12.13.

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

SECTION 11.14. GOVERNING LAW. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF NEW YORK APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO THE CONFLICTS OF LAW PRINCIPLES OF SUCH STATE.

[Remainder of page intentionally left blank; signature page follows.]

CERTAIN PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED BASED UPON A REQUEST FOR CONFIDENTIAL TREATMENT AND THE NON-PUBLIC INFORMATION HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION.

IN WITNESS WHEREOF, Seller and Purchaser have duly executed this Agreement as of the date first written above.

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Demetrios Kydonieus

Name: Demetrios Kydonieus

Title: Vice President, Strategy, Alliances & Transactions

SYNERGY PHARMACEUTICALS, INC.

By: /s/ Gary S. Jacob
Name: Gary S. Jacob
Title: President and Chief Executive Officer

Exhibit 23

Consent of Independent Registered Public Accounting Firm

Synergy Pharmaceuticals Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-163316, 333-177730 and 333-182271) of Synergy Pharmaceuticals Inc. and Subsidiaries (a development stage company) (the "Company") of our reports dated March 18, 2013, relating to the consolidated financial statements and the effectiveness of the Company's internal control over financial reporting which appears in this Form 10-K. Our report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
New York, New York
March 18, 2013

Exhibit 31.1

CERTIFICATION

I, Gary S. Jacob, certify that:

1. I have reviewed this annual report on Form 10-K of Synergy Pharmaceuticals, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 18, 2013

/s/ GARY S. JACOB
Gary S. Jacob
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Bernard Denoyer, certify that:

1. I have reviewed this annual report on Form 10-K of Synergy Pharmaceuticals, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 18, 2013

/s/ BERNARD DENOYER
Bernard Denoyer
Senior Vice President, Finance

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Synergy Pharmaceuticals Inc. (the "Company") on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gary S. Jacob, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 18, 2013

/s/ GARY S. JACOB
Gary S. Jacob
Chief Executive Officer

Exhibit 32.2

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Synergy Pharmaceuticals Inc. (the “Company”) on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Bernard Denoyer, Senior Vice President, Finance of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 18, 2013

/s/ BERNARD DENOYER
Bernard Denoyer
Senior Vice President, Finance