CALLISTO PHARMACEUTICALS INC
Form 10-K
March 31, 2010

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ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark one)

ý **ANNUAL REPORT under SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED: DECEMBER 31, 2009

o **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: 001-32325

CALLISTO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**12-3894575**
(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) 297-0010
(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**
None	

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

Title of class: **Common stock, $0.0001 par value**

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

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 o No ý

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 ý No o

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 o No o

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. ý

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $14,375,218 on June 30, 2009 (based on $0.28 per share, the closing price on that day).

As of March 30, 2010 the registrant had a total of 54,024,778 shares of Common Stock outstanding.

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CALLISTO PHARMACEUTICALS, INC.

(A Development Stage Company)

FORM 10-K

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PART I

This Report on Form 10-K for Callisto Pharmaceuticals, Inc. may contain forward-looking statements. 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 elsewhere in this annual report on Form 10-K for the year ended December 31, 2009, 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 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. All drug candidates to treat GI disorders and diseases, currently SP-304 and SP-333, are being developed exclusively by Synergy Pharmaceuticals, Inc., our majority-owned subsidiary ("Synergy"). Use of the terms "we", "our" or "us" in connection with GI drug candidates discussed herein refer to research and development activities and plans of Synergy.

ITEM 1. BUSINESS.

GENERAL

Callisto Pharmaceuticals, Inc. (which may be referred to as "Callisto", "the Company", "we" or "us") was incorporated under the laws of the State of Delaware in May 2003. We operate through two subsidiary companies: Synergy and Callisto Research Labs, LLC, and we own two inactive subsidiaries, IgX, Ltd (Ireland) and Callisto Pharma, GmbH (Germany). Our principal offices are located at 420 Lexington Avenue, Suite 1609, New York, NY 10170.

We are a development stage biopharmaceutical company focused primarily on the development of drugs to treat gastrointestinal ("GI") disorders and diseases, rheumatoid arthritis (RA), neuroendocrine cancer (including advanced carcinoid cancer),and acute leukemia. Our lead drug candidates are as follows:

(1) SP-304, a guanylyl cyclase C ("GC-C") receptor agonist, to treat GI disorders, primarily chronic constipation ("CC") and constipation-predominant irritable bowel syndrome ("IBS-C").

(2) SP-333, a second generation GC-C receptor agonist, SP-333, now in pre-clinical development to treat gastrointestinal inflammatory diseases.

(3) Atiprimod, an orally administered drug with antiproliferative, anti-inflammatory and antiangiogenic activity.

(4) L-Annamycin, a novel compound from the anthracycline family of proven anti-cancer drugs, which has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced cardiotoxicity, or damage to the heart.

HISTORY

In March 2002, Callisto Pharmaceuticals, Inc. ("Old Callisto"), a non-public company, purchased 99.7% of the outstanding common shares of Webtronics, Inc., ("Webtronics") a public company for

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$400,000. Webtronics was incorporated in Florida on February 2, 2001 and had limited operations at December 31, 2002.

On April 30, 2003, pursuant to an Agreement and Plan of Merger dated March 10, 2003, as amended April 4, 2003, Synergy Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Synergy Pharmaceuticals, Inc. ("Synergy-DE") and Callisto Acquisition Corp., a wholly-owned subsidiary of Webtronics merged into Old Callisto (collectively, the "Merger"). As a result of the Merger, Old Callisto and Synergy-DE became wholly-owned subsidiaries of Webtronics. In connection with the Merger, Webtronics issued 17,318,994 shares of its common stock in exchange for outstanding Old Callisto common stock and an additional 4,395,684 shares in exchange for outstanding Synergy-DE common stock. In May 2003, Old Callisto changed its name to Callisto Research Labs, LLC ("Callisto Research") and Webtronics changed its name to Callisto Pharmaceuticals, Inc. and changed its state of incorporation from Florida to Delaware. Subsequently, 171,818 shares of common stock issued to former Synergy-DE shareholders were returned to us under the terms of certain indemnification agreements.

From inception through December 31, 2009, we have sustained cumulative net losses available to common stockholders of $109,779,780. Our losses have resulted primarily from expenditures incurred in connection with research and development activities, application and filing for regulatory approval of proposed products, stock-based compensation expense, patent filing and maintenance expenses, purchase of in-process research and development, outside accounting and legal services and regulatory, scientific and financial consulting fees, as well as non-cash accretion of dividends attributable to the beneficial conversion rights of convertible preferred stock. From inception through December 31, 2009 we have not generated any revenue from operations. We expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products, and do not expect to have such for several years, if at all.

Our product development efforts are in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of not completing 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, the nature and timing of costs and competing technologies being developed by organizations with significantly greater resources.

Recent Developments

On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

On July 14, 2008, we entered into an Exchange Agreement dated July 11, 2008 ("Exchange Agreement"), as amended and effective on July 14, 2008, with Pawfect Foods, Inc. ("Pawfect"), Synergy-DE and other holders of Synergy-DE common stock. According to the terms of the Exchange Agreement, Pawfect acquired 100% of the common stock of Synergy-DE, from us and the other holders of Synergy-DE, in exchange for 45,464,760 shares of Pawfect's common stock representing approximately 70% of Pawfect's outstanding common stock (the "Exchange Transaction"). We received 44,590,000 of the 45,464,760 shares of Pawfect's common stock exchanged for our ownership of

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Synergy-DE, representing 68% of Pawfect's outstanding common stock. The remaining 874,760 shares of Pawfect common stock exchanged for ownership of Synergy-DE were issued to certain executive officers of Synergy-DE who received their shares pursuant to a Repurchase Agreement with Synergy-DE dated July 3, 2008 and assumed by Pawfect. In connection with the Exchange Transaction Pawfect received $3,025,000 less transaction costs of $73,087, yielding net proceeds of $2,951,913 from two private placements, which we have recorded as an increase in additional paid-in capital.

Pawfect was a development stage company selling pet food products utilizing the internet, with immaterial operations at the date of the Exchange Agreement. On July 14, 2008, Pawfect discontinued its pet food business to focus all resources on continuing the development of drugs to treat GI disorders and diseases acquired in connection with the Exchange Agreement. 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 Agreement and changed its name to Synergy Pharmaceuticals, Inc. ("Synergy"). Synergy is now traded on the Over the Counter Bulletin Board under the symbol SGYP.OB.

PROPOSED PRODUCTS

SP-304 TO TREAT GI DISORDERS

We are currently developing SP-304, a synthetic hexadecapeptide designed to mimic the actions of the GI hormone uroguanylin, for the treatment of CC and IBS-C. SP-304 is an agonist of GC-C. The endogenous agonists of GC-C receptor are uroguanylin and guanylin, which were discovered as natriuretic hormones based on their structural similarity to bacterial enterotoxin, the peptide secreted by pathogenic *Escherichia coli* (***E.coli***) bacteria responsible for traveler's diarrhea.

SP-304 is a new member of a novel class of non-systemic drugs for treatment of CC, IBS-C and other GI disorders and diseases. SP-304 was developed by our scientists based on structure-function studies performed in-house. SP-304 is an analog of uroguanylin, a natural peptide hormone produced in the gut that is a key regulator of intestinal function. Uroguanylin works by activating the GC-C receptor on intestinal cells which promotes fluid and ion transport in the GI tract. Under normal conditions, this receptor is activated by the natural hormone uroguanylin and/or by a similar natural hormone guanylin.

Clinical Studies

On June 4, 2008, we initiated a Phase 1 clinical trial of SP-304 in volunteers. This first study was a double-blind, placebo-controlled, randomized single, oral, ascending-dose trial performed in 71 healthy male and female volunteers. The primary objective of the clinical trial was to characterize the safety, tolerability, pharmacokinetic and pharmacodynamic effects of the drug in healthy volunteers.

On December 9, 2008, we announced the completion of the Phase 1 clinical trial of SP-304 in healthy volunteers. Cohorts of volunteers were administered a single, oral dose of SP-304 ranging in dose from 0.1, 0.3, 0.9, 2.7, 5.4, 8.1, 16.2, 24.3 and 48.6 mg, respectively or given a matching placebo dose. No detectable SP-304 was observed in the plasma of any subject administered SP-304 throughout the range from 0.1-48.6 mg. Pharmacodynamic effects of SP-304 related to the frequency and consistency of bowel movements after SP-304 administration were studied, and trends were observed related to greater increases in the number of bowel movements and looser stools for SP-304 in comparison to placebo. These findings suggested a positive pharmacodynamic effect for SP-304 administration compared to placebo. Overall, SP-304 was safe and well tolerated throughout the single-dose range from 0.1-48.6 mg.

On March 19, 2010, we initiated a Phase 2a 14-day repeated-oral-dose, placebo-controlled, dose-escalation trial of SP-304 in CC patients. In addition our plan is to begin a Phase 2b 28-day

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repeated-oral-dose, placebo-controlled trial in SP-304 in CC patients in early 2011 and a Phase 2b 90-day repeated-oral-dose, placebo-controlled trial of SP-304 in IBS-C patients in the second quarter of 2011.

SP-333 TO TREAT ULCERATIVE COLITIS

A second generation GC-C receptor agonist, SP-333, is now in pre-clinical development to treat gastrointestinal inflammatory diseases such as UC. We plan to file an IND for SP-333 to treat UC in the fourth quarter of 2010. We previously showed that GC-C receptor agonists are efficacious in animal models of UC. In addition, we evaluated GC-C receptor agonists in two different animal models of UC, demonstrating that oral treatment of GC-C receptor agonists were effective in ameliorating GI inflammation in mouse models of experimental colitis. GC-C receptor agonists appear to produce anti-inflammatory activity via a novel cGMP-mediated mechanism that downregulates pro-inflammatory cytokines.

Development Plan

Our plan of operations for the next twelve months is to focus primarily on the clinical trial development of SP-304 to treat CC, and SP-333 to treat UC.

We plan to initiate a Phase 1 clinical trial of SP-333 in volunteers in the fourth quarter of 2010. We expect to follow this trial in 2011 with a Phase 1b single-dose trial in UC patients to evaluate safety and pharmacokinetics of orally administered SP-333 in UC patients.

Manufacturing of our Product Candidates

We do not have manufacturing capabilities. We currently use contract manufacturers for the manufacturing of SP-304 and SP-333. Accordingly, unless or until we develop or acquire sufficient manufacturing capabilities, we will depend on third parties to manufacture SP-304, SP-333 and any future products that we may develop or acquire. We are in the process of seeking long-term commercial supply contracts with active pharmaceutical ingredient manufacturers, and we anticipate that we will be able to negotiate these third-party agreements on commercially reasonable terms. We are in the process of working with third-party manufacturers to develop the ability to produce SP-304 in accordance with current good manufacturing practices, or GMP, on a sufficient scale to meet our future commercial needs. It is a fundamental part of our commercial strategy to maintain two or more active pharmaceutical ingredient suppliers to ensure continuity in our supply chain.

At present we have 1.5 kg of SP-304 in production under GMP conditions, which will be used for non-clinical work to support further human studies. We also have sufficient supplies of GMP-grade SP-304 for our Phase 2 clinical trials in CC. Additionally, we have over 400 grams of non-GMP SP-333 available to support the non-clinical work needed for filing an IND on SP-333 in the third quarter of 2010. Manufacturing of GMP-scale SP-333 is currently underway. This material is needed for the clinical trial of SP-333 in healthy volunteers scheduled to begin in 2010.

ATIPRIMOD

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement (the "Original License") with AnorMED Inc. ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod patent rights. The Original License provided for aggregate milestone payments of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy was obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. These annual maintenance fee payments

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under the Original License were made in January 2004, 2005, 2006 and 2007 and recorded as research and development expense.

On December 31, 2007, we and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which the parties amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties. In return for the reduced future payments to Genzyme, we agreed to pay upfront fees which were recorded as a liability and expensed on December 31, 2007. As of December 18, 2008, $650,000 of these upfront fees remained due and payable.

On December 19, 2008, we entered into a Technology Assignment Agreement (the "Agreement") with AnorMED pursuant to which AnorMED transferred and assigned to us all of AnorMED's right, title and interest in and to all patents and patent applications with respect to Atiprimod in addition to all trade secrets, technical reports and data concerning Atiprimod and any analogs or derivatives in return for a cash payment of $650,000, which payment settled the upfront fees owed from December 31, 2007 Amended and Restated License Agreement. In addition the Agreement specified that the Amended and Restated License Agreement between us and AnorMED dated December 31, 2007, with respect to which AnorMED licensed to us certain patent rights and technology related to Atiprimod, was terminated with no additional amounts due.

Atiprimod is one of a class of compounds known as azaspiranes and was originally developed as a potential treatment for RA based on encouraging data from a number of animal models of arthritis and autoimmune indications. The development of this drug originated with a partnership between AnorMED and Smith Kline Beecham ("SKB") that led to the successful filing of an IND, and completion of three Phase I clinical trials involving a total of 63 patients. The drug successfully completed both single and multiple dose Phase I clinical trials in patients with RA. Both trials evaluated the safety and pharmacokinetics (how the body takes up and eliminates drugs) of Atiprimod and showed that the drug is well tolerated. In the third Phase I clinical trial, the drug was found to be well tolerated in an open label extension study performed with 43 patients from the second two studies, with patients on the drug for as long as one year.

Completed Clinical Studies

Atiprimod successfully completed single and multiple dose Phase I clinical trials in patients with RA. In the initial Phase I study, 28 patients were given single escalating doses of drug (0.002 - 1.0 mg/kg), with a four month follow-up. Atiprimod was well tolerated, displaying no clinically relevant changes in any laboratory parameters. In particular, liver function tests remained in the normal range. The second Phase I study involved a 28-day multiple-dose-rising study in 35 RA patients. The study evaluated the effect of food on bioavailability, or the concentration of drug in the body, as well as the safety and pharmacokinetics of repeat dosing. Dosages included 0.1, 1.0, 5.0, and 10 mg/day plus a 14-day cohort at 30 mg/day, with four month follow-up. All doses were well tolerated and clinical tests were unremarkable. Significantly, reductions in tender and swollen joint counts were noted in a number of subjects during the course of the dosing period. Individuals from the two Phase I safety studies were also involved in a Phase I open-label extension trial at five mg/day dosage. Forty-three patients entered the study and remained on the drug as long as 12 months. Clinical laboratory results for all patients were unremarkable, in particular liver enzyme levels remained within the normal range in all patients throughout the study period.

Development Status

On November 7, 2006, we announced the initiation of a multi-center open-label Phase II clinical trial of Atiprimod for low-to-intermediate grade neuroendocrine cancers, primarily in advanced

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carcinoid cancer patients. This trial is based on earlier encouraging clinical results from a Phase I trial of Atiprimod in advanced cancer patients that showed stable disease and disease-related symptom relief in patients with advanced carcinoid cancer.

On May 16, 2008, we announced interim data from the company's ongoing open-label Phase II clinical trial of Atiprimod to treat low to intermediate grade neuroendocrine carcinoma (advanced carcinoid cancer). Overall, the interim results suggested that Atiprimod is an active and well tolerated drug in the treatment of carcinoid cancer. In this interim analysis, 25 of 46 enrolled patients had sufficient data available for evaluation. The median follow up of the patients was 6 months (range 2 to over 12 months). All patients enrolled in this study had evidence of progressing disease in the 6 months preceding enrollment. Of the evaluable patients, 92% had stable disease as best response per standard RECIST criteria, with a median duration of 6 months. Actuarial progression free survival at 6 months was 76% and at 12 months it was 50%. There were no objective RECIST responses for tumor regression in the analyzed cohort. At the time of the announcement, 7 patients had completed all 12 planned cycles of Atiprimod therapy with stable disease and had entered an extension trial to continue treatment. In this slow growing cancer, Atiprimod appeared to show an ability to stabilize disease progression and to reduce the symptoms of this disease, with a side effect profile that was generally well tolerated, with reversible increases in liver transaminases as the most notable adverse event.

On January 27, 2009, we announced that we were focusing all further development of Atiprimod towards the treatment of RA. We recognized that although the ongoing Phase II clinical trial of Atiprimod in advanced carcinoid cancer gave encouraging results, the data were not sufficiently demonstrative to warrant further development of Atiprimod in this indication. We announced, instead, our intention that based on Atiprimod's demonstrated favorable clinical safety profile, robustly supported by earlier studies of Atiprimod in RA patients, as well as by the recent oncology trials in advanced carcinoid cancer patients, where the drug was dosed at levels and frequencies considerably higher than anticipated for use in RA, we believe that Atiprimod holds significant promise as a new class of orally-administered, disease-modifying agent in RA.

Manufacturing of Atiprimod

A practical, efficient and cost effective method for producing Atiprimod on a commercial scale was originally developed by SKB. In the course of this work, a new dimaleate salt form was developed. A portion of the 7 kilos of Atiprimod drug substance, available from SKB, was used as the source for generating the Atiprimod dimaleate drug product presently being used in the Phase I/IIa clinical study. Several lots of drug substance were re-qualified to meet current FDA approved release specifications. The full package of fully validated analytical methods developed by SKB was transferred to a contract research organization used by us to perform all analytical tests. One large-scale GMP production run of Atiprimod dimaleate led to the successful release of 10 Kg of material available for future Phase II clinical studies.

Orphan Drug Status of Atiprimod

On January 6, 2004, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of multiple myeloma. On September 26, 2006, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to Atiprimod for the treatment of carcinoid tumors. The FDA grants orphan drug status for drug candidates that are intended to treat rare life-threatening diseases that, at the time of application, affect no more than 200,000 patients in the United States. The drug must have the ability to provide significant patient benefit over currently available treatment or fill an unmet medical need. Orphan drug designation entitles us to seven years of market exclusivity in the United States of America, and ten years of market exclusivity in Europe, upon FDA marketing approval, provided that we continue to meet certain conditions established by the FDA. Once the FDA grants

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marketing approval of a new drug, the FDA will not accept or approve other applications to market the same medicinal product for the same therapeutic indication. Other incentives provided by orphan status include certain tax benefits, eligibility for research grants and protocol assistance. Protocol assistance includes regulatory assistance and possible exemptions or reductions of certain regulatory fees.

L-ANNAMYCIN

On August 12, 2004 we entered into a worldwide exclusive license agreement with The University of Texas M.D. Anderson Cancer Center to develop and commercially exploit the L-Annamycin patent rights. L-Annamycin, an anthracycline drug for leukemia therapy, has a novel therapeutic profile, including activity against drug resistant tumors and significantly reduced toxicity.

Completed Clinical Studies

L-Annamycin was evaluated previously by Aronex Pharmaceuticals, Inc. in 3 clinical trials: 1) a Phase I clinical trial in 36 patients with relapsed solid tumors, 2) a Phase II clinical trial in 13 patients with doxorubicin-resistant breast cancer, and 3) a Phase I/IIa trial in 20 patients with relapsed/refractory acute myelogenous leukemia (AML) and acute lymphocytic leukemia (ALL). In the initial Phase I study, L-Annamycin was administered by a single 1- to 2-h intravenous infusion at 3-week intervals. Thirty-six patients with relapsed solid tumors were treated and 109 treatment courses were administered at doses ranging from 3 to 240 mg/m2. No cardiotoxicity was seen on biopsy of heart tissue of four patients studied. The maximum tolerated dose (MTD) for L-Annamycin in solid tumor patients was found to be 190 mg/m2. A second Phase II study of L-Annamycin was performed in 13 women with doxorubicin-resistant breast cancer. The median number of prior chemotherapy regimes was two, and six patients had two or more organ sites of involvement. L-Annamycin was administered at 190-250 mg/m2 as a single i.v. infusion over 1-2 h every 3 weeks. Of the 13 patients, 12 had clear deterioration and new tumor growth after one or two courses.

The potential of a less cardiotoxic drug that was active against multi-drug resistant tumors led to a third trial in relapsed leukemia patients (both AML and ALL). The trial involved 20 patients with relapsed/refractory AML (n=17) or ALL (n=3). The conclusions drawn from the trial were that L-Annamycin was safe, well tolerated and showed potential clinical activity in patients with acute leukemias, and that further evaluation of this novel anthracycline in patients with hematopoietic, or blood borne, malignancies was clearly warranted.

Development Status

We began a Phase I clinical trial at The University of Texas M.D. Anderson Cancer Center in adult relapsed or refractory ALL patients on December 1, 2005. Additional sites enrolled in this study include the Roswell Park Cancer Institute (Buffalo, NY) and the Montefiore Medical Center (New York, NY). The single-arm, open-label L-Annamycin trial was designed to enroll patients in a dose escalation Phase I portion followed by 10 patients at a final fixed dose in the Phase II portion once the maximum tolerated dose (MTD) was determined. A major goal of the trial was to confirm the MTD reported from the previous sponsor for use in adult ALL patients. The clinical data from our studies indicated that the MTD reported by the previous sponsor which indicated that patients could be dosed as high as 280 mg/m2/day for 3 consecutive days in ALL patients was too high. We utilized a uniform validated reconstitution method that we believe delivers a more uniform liposomal drug product when infused into patients. This infusion methodology was utilized across all study sites. We established an MTD of 150 mg/m2/day, given for 3 consecutive days, in the adult trial and finished dosing of 10 patients at this MTD value. The clinical data on these patients, however, did not support further clinical evaluation of L-Annamycin as a single agent to treat relapsed or refractory adult acute leukemia patients, and we do not plan any further trial with L-Annamycin.

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In February, 2007, we opened a Phase I trial of L-Annamycin in pediatric relapsed or refractory ALL or AML patients. Based on the information from the ongoing adult trial, we initiated this trial at 130 mg/m2/day given for three consecutive days. The trial was a multi-center, open-label, single-agent, dose-escalation study that utilized four clinical sites in the U.S. Due to the low number of patients with this disease, we were only able to enroll 3 patients in total, all at 130 mg/m2/day, and never achieved an MTD in children. Due to poor enrollment plus the decision to suspend further development of L-Annamycin in adults, we suspended any further work on L-Annamycin in acute leukemia as of December 31,2008.

Manufacturing of Annamycin

An improved manufacturing method for Annamycin was developed at Antibioticos S.p.A., our sole commercial supplier of GMP ("Good Manufacturing Practice") drug substance.

Orphan Drug Status of L-Annamycin

On June 24, 2005, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to L-Annamycin for the treatment of acute lymphoblastic leukemia. On June 28, 2005, we announced that the Office of Orphan Products Development of the FDA granted orphan drug designation to L-Annamycin for the treatment of acute myeloid leukemia.

DEGRASYNS

On January 10, 2006, we entered into a license agreement with the University of Texas M.D. Anderson Cancer Center whereby we were granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). Degrasyns are a second-generation class of tyrphostins developed by scientists at the University of Texas M.D. Anderson Cancer Center that have a novel anti-cancer mechanism-of-action that centers on their ability to selectively degrade key proteins that are involved in tumor cell proliferation and survival. The intention was to work with key scientists at the University of Texas M.D. Anderson Cancer Center to bring forward a pre-clinical candidate for development in the clinic. All in-house work on this program was discontinued as of December 31, 2008.

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 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;

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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 an 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

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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 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

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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.

COMPETITION

The biopharmaceutical industry is characterized by rapidly evolving technology and intense competition. Our competitors focusing on GI include major pharmaceutical and biotechnology companies such as Ironwood (Microbia), Sucampo/Takeda and Novartis. Our competitors focusing on hematological oncology include major pharmaceutical and biotechnology companies such as Microbia Inc., Hana Biosciences Inc., SGX Pharmaceuticals, Inc., Sunesis Pharmaceuticals, Inc. and Vion Pharmaceuticals, Inc. 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 venture. 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 expenses consist primarily of costs associated with (i) clinical development team salaries and staff costs, (ii) application and filing for regulatory approval of our proposed products, (iii) regulatory and scientific consulting fees, (iv) clinical and patient costs for product candidates in on-going trials, (v) sponsored pre-clinical research, (vi) royalty and license fee payments, (vii) legal and professional fees associated with filing and maintaining our patent and license rights to our proposed products, (viii) clinical drug substance and (ix) acquired in-process research and development. We expense all research and development costs as they are incurred and we expect our research and development expenses to increase significantly in the future as we develop our product candidates. Research and development expenses were $3,936,474 for the twelve months ended

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December 31, 2009, compared to $5,449,721and $6,507,978 for the twelve months ended December 31, 2008 and 2007, respectively.

On April 1, 2005 we were awarded an $885,641 biodefense partnership grant from the NIAID to develop a monoclonal antibody and vaccine against bacterial superantigen toxins over a two year period. During the twelve months ended December 31, 2009, 2008 and 2007 we received $0, $30,000 and $260,853, respectively, which has been reported on our Consolidated Statements of Operations as a separate line item entitled "Government Grant". We terminated in-house work on this program upon expiration of the research grant in April 2008, and we have had no funding remaining since December 31, 2008.

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. Accordingly, patents or other proprietary rights are an essential element of our business. We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties to the parties in addition to upfront or milestone payments, and to expend certain minimum resources to develop these technologies. 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.

As of December 31, 2009, we are the assignee or exclusive licensee of 9 pending patent applications and 11 issued patents in the United States, and currently we have approximately 150 issued or pending foreign patent applications. We seek patent protection of inventions originating from our ongoing research and development activities that are commercially important to our business. Our composition-of-matter and use patent on SP-304 issued on May 9, 2006 expires in 2023. Our composition-of-matter patents for L-Annamycin and Atiprimod expire in 2017 and 2016, respectively. Our formulation patents for L-Annamycin and Atiprimod dimaleate salt both expire in 2016.

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

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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.

LICENSE AGREEMENTS

On January 10, 2006, we entered into a Patent and Technology License Agreement with The University of Texas M.D. Anderson Cancer Center. Pursuant to the license agreement, we were granted the exclusive right to manufacture, have manufactured, use, import, offer to sell and/or sell anti-cancer compounds called tyrphostins (renamed Degrasyns). We paid a nonrefundable license fee of $200,000 upon execution of this agreement and we are obligated to pay annual license maintenance fees to The University of Texas M.D. Anderson Cancer Center. We are also obligated under this agreement to pay for legal fees and expenses associated with establishing and protecting the patent rights worldwide.

We also agreed to pay The University of Texas M.D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $1,750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from January 10, 2006 until the end of the term for which the patent rights associated with the licensed technology have expired. If the first pending patent is issued, the agreement is projected to expire in 2024. In addition, at any time after January 10, 2008, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or are actively and effectively attempting to commercialize the licensed technology.

On August 12, 2004, we entered into a world-wide license agreement with The University of Texas M.D. Anderson Cancer Center to research, develop, sell and commercially exploit the patent rights for L-Annamycin. Consideration paid for this license amounted to $31,497 for reimbursement of out-of-pocket costs for filing, enforcing and maintaining the L-Annamycin patent rights and a $100,000 initial license fee. We also agreed to pay The University of Texas M. D. Anderson Cancer Center royalties based on net sales from any licensed products, plus aggregate milestone payments of up to $750,000 based upon achieving certain regulatory submissions and approvals. The term of the agreement is from August 12, 2004 until November 2, 2019. Under the terms of the license agreement, we are required to make certain good faith expenditures towards the clinical development of at least one licensed product within the two year period after March 2005. In addition, at any time after August 12, 2009, The University of Texas M.D. Anderson Cancer Center has the right to terminate the license if we fail to provide evidence within 90 days of written notice that we have commercialized or we are actively and effectively attempting to commercialize L-Annamycin.

On August 28, 2002, and as amended on May 23, 2003, Synergy entered into a worldwide license agreement (the "Original License") with AnorMED Inc. ("AnorMED") to research, develop, sell and commercially exploit the Atiprimod (SKF 106615) patent rights. The Original License provided for aggregate milestone payments of up to $14 million based upon achieving certain regulatory submissions and approvals for an initial indication, and additional payments of up to $16 million for each additional indication based on achieving certain regulatory submissions and approvals. Commencing on January 1, 2004 and on January 1 of each subsequent year Synergy was obligated to pay AnorMED a maintenance fee of $200,000 until the first commercial sale of the product. These annual maintenance fee payments under the Original License were made in January 2004, 2005, 2006 and 2007 and recorded as research and development expense.

On December 31, 2007, we and Synergy entered into an Amended and Restated License Agreement with AnorMED Corporation ("AnorMED"), a wholly-owned subsidiary of Genzyme Corporation ("Genzyme"), pursuant to which the parties amended the Original License agreement for Atiprimod to eliminate all future maintenance fees and milestone payments and reduce future royalties to single digits. In return for the reduced future payments to Genzyme, we agreed to pay upfront fees

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which were recorded as a liability and expensed on December 31, 2007. As of December 18, 2008 $650,000 of these upfront fees remained due and payable. On December 19, 2008, we entered into a Technology Assignment Agreement (the "Agreement") with AnorMED pursuant to which AnorMED transferred and assigned to us all of AnorMED's right, title and interest in and to all patents and patent applications with respect to Atiprimod in addition to all trade secrets, technical reports and data concerning Atiprimod and any analogs or derivatives in return for a cash payment of $650,000, which payment settled the upfront fees owed from the December 31, 2007 Amended and Restated License Agreement. In addition the Agreement specified that the Amended and Restated License Agreement between us and AnorMED dated December 31, 2007, with respect to which AnorMED licensed to us certain patent rights and technology related to Atiprimod, was terminated with no additional payments due.

On August 20, 1996, we entered into a license agreement to research, develop, sell and commercially exploit certain Rockefeller University licensed patents covering peptides and antibodies useful in treating toxic shock syndrome and septic shock. We agreed to work toward commercialization of products related to these patents as evidenced by a minimum expenditure of approximately $210,000 per year, plus milestone payments and royalties of between 2% and 3% of annual net sales and will pay Rockefeller 30% of any sublicense fee paid by sublicenses. The licensed patents under this agreement are the subject of research that was funded by the NIAID grant awarded to us on April 1, 2005 for $885,641over two years. In addition, on July 2, 2001, we entered into a license agreement for two additional patents related to the regulation of exoproteins in staphylococcus aureus. On February 14, 2008, we terminated both the August 1996 and July 2001 license agreements.

EMPLOYEES

As of March 31, 2010, we had 6 full-time and 3 part-time employees. We believe our employee relations are satisfactory.

CALLISTO WEBSITE

Our website address is **www.callistopharma.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, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or 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 2. PROPERTIES.

Our corporate headquarters totals approximately 5,500 square feet, in two suites 1609 and 1701, located at 420 Lexington Avenue, New York, NY The term of the leases at 420 Lexington Avenue expire on June 30, 2011 and September 30, 2010. We also occupy a small laboratory and several offices, totaling approximately 1,000 square feet, in the Bucks County Biotechnology Center in Doylestown, Pennsylvania under a lease expiring August 31, 2010.

We believe our existing facilities are well maintained, in good operating condition, and that our existing and planned facilities will be adequate to support our operations for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

In June 2007, we filed a complaint against Dr. Donald Picker ("Picker") in the Supreme Court of the State of New York alleging breach of his employment agreement, fraud, conversion and related claims. We were seeking $80 million in damages from Picker. During 2008 Picker moved for a summary judgment and on May 5, 2009 the court ruled in favor of Picker dismissing our complaint. On

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February 22, 2010 we filed a brief with the Appellate Division of the New York Supreme Court (the "Appeal") seeking the summary judgment be reversed and the complaint be reinstated. Our Appeal, which also requests immediate jury trial, is still pending.

On December 22, 2009, through our subsidiary Synergy Advanced Pharmaceuticals, Inc., we 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 non-disclosure provisions and non-compete 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. In addition, we are requesting an assignment of all patents and other intellectual property rights defendants currently hold relating to any inventions obtained in breach of the agreements as well as compensatory, consequential and punitive damages.

We are not a party to any other pending legal proceedings.

ITEM 4. RESERVED.

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PART II

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

MARKET PRICES

Our common stock was quoted on the American Stock Exchange ("AMEX") under the symbol "KAL" from October 25, 2004 until July 14, 2008. Our common stock currently trades on the Over the Counter Bulletin Board under the symbol "CLSP.OB".

The following table shows the reported high and low closing prices per share for our common stock as reported on the AMEX prior to July 14, 2008 and as reported on the Over the Counter Bulletin Board subsequent to July 14, 2008.

	2009		2008	
	High	Low	High	Low
First Quarter	$ 0.15	$ 0.07	$ 0.62	$ 0.36
Second Quarter	$ 0.28	$ 0.06	$ 0.40	$ 0.24
Third Quarter	$ 0.45	$ 0.20	$ 0.24	$ 0.05
Fourth Quarter	$ 0.42	$ 0.18	$ 0.14	$ 0.03

HOLDERS OF COMMON STOCK

As of March 31, 2010 we had 408 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.

EQUITY COMPENSATION INFORMATION

The following table summarizes information about our equity compensation plans as of December 31, 2009.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options and Warrants (a)	Weighted-Average Exercise Price of Outstanding Options and Warrants	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity Compensation Plans Approved by Stockholders	5,170,483	$ 1.69	4,275,000
Equity Compensation Plans Not Approved by Stockholders(1)	87,167,131	0.10	
Total	92,337,614	$ 0.14	4,275,000

(1) Consists of 2,324,555 stock options not subject to any of our stock option plans and 84,842,576 warrants. These non-plan stock options and warrants have been primarily issued in conjunction with our private placements of common stock and consulting services agreements.